Supreme Court, U.S.
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No. 03-

IN THE

Supreme Court of the United States

FOREST LABORATORIES, INC. and ONY INC.,

Petitioners,

v.

ABBOTT LABORATORIES,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

This petition is one of two submitted within one week in different cases seeking review of the Federal Circuit's "bright-line" rule limiting the district courts' discretion to award reasonable attorney fees as a result of misconduct by a party in a patent case. The questions presented here are:

1. Did the Court of Appeals for the Federal Circuit err in establishing a "bright-line" rule defining only certain conduct as "exceptional" under 35 U.S.C. § 285 and thereby limiting the discretion of federal district courts to prevent gross injustice by awarding attorney fees to a prevailing party because of pre-litigation misconduct?

2. Did the Court of Appeals for the Federal Circuit err in holding that clear and convincing evidence of pre-litigation misconduct that gave rise to a finding of equitable estoppel cannot, as a matter of law, make a patent case "exceptional"?

CORPORATE DISCLOSURE STATEMENT

Petitioners Forest Laboratories, Inc. and ONY Inc. have no parent companies. There are no publicly-held companies that own ten percent or more of the stock of the petitioners.

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FOREST LABORATORIES, INC. and ONY INC.,

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ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

Petitioners Forest Laboratories, Inc. and ONY Inc. respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-12a) is reported at 339 F.3d 1324. The opinions of the United States District Court for the Western District of New York (Pet. App. 13a-31a and 32a-90a) are unreported.

STATEMENT OF JURISDICTION

The judgment of the court of appeals was entered on August 7, 2003. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

This case presents an issue of how Section 285 of Title 35 of the United States Code is interpreted. Section 285 provides that:

> The court in exceptional cases may award reasonable attorney fees to the prevailing party.

STATEMENT OF THE CASE

The court of appeals' decision eviscerates the intent of 35 U.S.C. § 285 to compensate the wronged party. After a four-month trial, the district court awarded attorney fees to petitioners Forest Laboratories, Inc. ("Forest") and ONY Inc. ("ONY"), under § 285. The district court found by clear and convincing evidence that respondent Abbott Laboratories ("Abbott") had engaged in bad-faith conduct by repeatedly encouraging Forest and ONY over an eleven-year period to pursue the development of Infasurf® — a surfactant replacement drug used to treat the lungs of premature

babies. Abbott did so because it "was betting on two horses." Pet. App. 22a. Before its own drug — Survanta® — received regulatory approval, Abbott was encouraging ONY to proceed with the development of Infasurf® so that it could rely on Infasurf® as its backup drug in the event that Survanta® failed to obtain approval. But once Survanta® was approved by the FDA, Abbott did an about-face and charged ONY and Forest with infringement, prompting the suit that ultimately led to the attorney fees award.

The district court found that petitioners did not infringe and that Abbott was barred by equitable estoppel from asserting its patents against petitioners. After finding clear and convincing evidence that Abbott had acted in bad faith, the district court awarded Forest and ONY fees and expenses to avoid a "gross injustice" and to deter other companies from similar conduct in the future.

The court of appeals reversed. Announcing a new "bright-line" rule, it held that "exceptional cases" are ***only*** those involving misconduct during litigation, inequitable conduct before the patent office, willful infringement, or a frivolous suit. It concluded that all other types of pre-litigation misconduct, such as Abbott's bad-faith conduct, which led to a finding of equitable estoppel, cannot, as a matter of law, be deemed "exceptional."[1]

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1. In *McNeil-PPC, Inc.* v. *L. Perrigo Co.*, 337 F.3d 1362 (Fed. Cir. 2003), also a case involving pharmaceuticals, decided six days before the ruling in this case, the Federal Circuit also reversed a district court's award of attorney fees to a prevailing alleged patent infringer for failure to satisfy its new bright-line test. The Eastern District of Pennsylvania did not find that McNeil had committed inequitable conduct before the Patent Office, but awarded attorney fees to Perrigo based on a finding,

(Cont'd)

The court of appeals' decision is contrary to the statutory intent of 35 U.S.C. § 285 and to the treatment by another circuit court of appeals of the analogous statute in trademark.

The court of appeals justified its treatment of Abbott's pre-litigation conduct on the grounds that "the consequence of estoppel is loss of the cause of action." Pet. App. 9a. This, however, does nothing to compensate petitioners for the substantial fees they incurred and for the time their product was delayed because of Abbott's misconduct. The court of appeals' rationale simply undermines the purpose of § 285, which is to prevent gross injustice to the harmed party. The award of fees contemplated by § 285 is not a mere technicality, but rather a part of a legislative provision that regulates the course of conduct that ultimately becomes the subject of litigation.

A. *Statutory Framework.* The question in this case is straightforward: may the court of appeals create a rigid definition of "exceptional case" that limits the circumstances under which the district court may exercise its discretion to award attorney fees? Section 285 of the Patent Act is the statutory provision addressed to attorney fees. It provides, in its entirety, that "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285 (2001).

(Cont'd)
which the court of appeals found was "not clearly erroneous," that McNeil prosecuted the pertinent patent applications with "'studied and deceptive ignorance.'" *Id.* at 1371. The court of appeals, however, held that because McNeil's misconduct did not rise to the level of "clear and convincing evidence of inequitable conduct [before the PTO] or misconduct during litigation," it could not result in an award of attorney fees because it was not one of its identified bright-line "'exceptional'" circumstances. *Id.* at 1372. Perrigo has recently filed a petition for a writ of certiorari also seeking this Court's review of the court of appeals' new bright-line rule.

Section 285 was enacted to prevent a gross injustice to a prevailing accused infringer and was not limited simply to compensate a prevailing patentee. Patent Rights – Protection, S. Rep. No. 79-1503 (June 14, 1946), *reprinted in* 1946 U.S.C.C.A.N. 1386-87. Prior to 1946, attorney fees were not awarded in patent cases. *Id.*; compare Patent Rights – Protection, ch. 726, Pub. L. No. 79-587 (Aug. 1, 1946), *reprinted in* 1946 U.S.C.C.A.N. 744, with 35 U.S.C. § 70 (1929). A patentee could recover only profits and damages. Patent Rights – Protection, S. Rep. No. 79-1503 (June 14, 1946), *reprinted in* 1946 U.S.C.C.A.N. 1387.

In 1946, an amendment to the damages section of the patent statute, then 35 U.S.C. § 70 (section 4921 of the revised statutes), included a provision that "[t]he court may in its discretion award reasonable attorney's fees to the prevailing party upon the entry of judgment on any patent case." Patent Rights – Protection, ch. 726, Pub. L. No. 79-587 (Aug. 1, 1946), *reprinted in* 1946 U.S.C.C.A.N. 744; 35 U.S.C. § 70 (1951). The 1946 Note of the Senate Committee on Patents states that "the provision relating to attorney's fees is made discretionary with the court." Patent Rights – Protection, S. Rep. No. 79-1503 (June 14, 1946), *reprinted in* 1946 U.S.C.C.A.N. 1387. The Committee added that

> the discretion given the court in this respect . . . will discourage infringement of a patent by anyone thinking that all he would be required to pay if he loses the suit would be a royalty. The provision is also made general ***so as to enable the court to prevent a gross injustice to an alleged infringer***.

Id. (emphasis added).

The 1952 Patent Act placed the attorney fees provision in 35 U.S.C. § 285 and amended it to its current form. 35 U.S.C. § 285 (1954). It did not substantively change the provision. 35 U.S.C. § 285, Revision Note, *reprinted in* 1952 U.S.C.C.A.N. 2403, 2423. The Revised Note states that § 285 "is substantially the same as the corresponding provision in R.S. 4921 [the 1946 version]; 'in exceptional cases' has been added as expressing the intention of the present statute as shown by its legislative history and as interpreted by the courts." *Id.*

Like the patent statute, the Lanham Act provides that "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party" in a trademark action. 15 U.S.C. § 1117(a) (Supp. 2003).

B. *This Litigation.* Petitioner ONY developed Infasurf®, the first lung surfactant replacement therapy used in the United States for treating respiratory distress syndrome in premature babies. Infasurf® utilizes as its active ingredient calf lung surfactant extract ("CLSE"). Beginning in 1983, ONY discussed CLSE with respondent Abbott. Between 1983 and 1991, Abbott actively encouraged petitioner ONY to pursue the development and clinical testing of CLSE and was fully aware that they intended to commercialize it. Abbott also knew in June 1991 that ONY and Forest became partners to further develop and market Infasurf®.

Abbott is the exclusive licensee of U.S. Patent Nos. 4,338,301 and 4,397,839 owned by Tokyo Tanabe Company Ltd. ("the Tanabe patents"). Abbott did not raise the question of possible infringement by CLSE of the Tanabe patents until it wrote to Forest in June 1994 — eleven years after Abbott first met with ONY to discuss CLSE. In fact, in 1984, Abbott conducted a patentability search for Infasurf® and led Forest

and ONY to believe that Infasurf® was not covered by any patents — including the Tokyo Tanabe patents. Abbott was aware that ONY was then telling the world that Infasurf® was not covered by patents and Abbott did not say anything contrary.

Abbott did not raise its infringement allegations until a decade later. At that time, ONY and Forest provided Abbott with samples of Infasurf® and a memorandum detailing why Infasurf® did not infringe. When Abbott continued threatening litigation for more than one and one-half years, Forest and ONY filed suit for a declaratory judgment in March 1996. After more than three years of litigation, the district court found that Infasurf® did not infringe the Tanabe patents — on the same grounds set forth in the non-infringement memorandum — and that Abbott was equitably estopped from asserting those patents against ONY and Forest. The court of appeals affirmed the judgment of no infringement and, having done so, declined to reach the issue of equitable estoppel.

Following the appeal, the district court granted ONY and Forest's motion for attorney fees, finding by clear and convincing evidence that Abbott had acted in bad faith. Pet. App. 13a-31a. It held that "Abbott misled ONY and Forest into reasonably believing that Abbott did not intend to enforce the Tokyo Tanabe patents against them" (Pet. App. 22a) and that Abbott had pursued its allegations of infringement "with a reckless disregard for the facts in an attempt to prevent Infasurf® from reaching the market." Pet. App. 25a.

In its separate opinion holding that Abbott was equitably estopped, which it incorporated by reference into its opinion awarding attorney fees, the district court concluded that

"Abbott's failure to mention possible infringement before 1994 was sufficiently misleading to amount to bad faith." Pet. App. 68a. The district court highlighted numerous specific examples of Abbott's misleading conduct from 1983 to 1991, and catalogued that conduct as: "Initial Encouragement and Patentability Search"; "Contacts Between June 1984 and April 1986"; "April 1986 Meeting"; and "Contacts Between 1987 and 1991." Pet. App. 51a-59a. The district court also described how "Abbott monitored CLSE, ONY and Forest" for many years but did not allege infringement. Pet. App. 59a.

The district court, in fact, characterized Abbott's conduct as "betting on two horses," meaning it was seemingly cooperating with petitioners while developing its own surfactant product. Pet. App. 22a. Abbott did so to remain free to finalize a collaboration with petitioners if its own product — Survanta® — failed to obtain FDA approval. Pet. App. 22a-23a.

Abbott never offered an adequate explanation for its conduct. Pet. App. 23a. Abbott declined to call the three Abbott employees from its witness list who would have been in the best position to explain Abbott's actions (if the actions could have been explained). Pet. App. 23a. As the district court observed, "once [ONY and Forest] put forth sufficient evidence to establish an equitable estoppel defense . . . [i]t was up to Abbott to either rebut such evidence or run the risk of an adverse verdict. Abbott chose the latter option." Pet. App. 23a.

The district court concluded that "Abbott's bad faith conduct makes this an 'exceptional' case for purposes of § 285, and that Abbott should be required to pay attorneys'

fees in order to prevent a gross injustice to ONY and Forest and to deter Abbott and other patentees from similar conduct in the future." Pet. App. 27a.

On appeal, Abbott argued, among other things, "that its private pre-litigation conduct was an inappropriate ground on which to base a finding of exceptionality." Pet. App. 6a. Forest and ONY maintained that a finding of exceptionality based on pre-litigation misconduct was within the discretion of the district court, and that Abbott had presented no legal support to the contrary. Pet. App. 7a.

The court of appeals reversed. The court of appeals "agree[d] with Abbott that the district court erred in awarding attorney fees to ONY and Forest." Pet. App. 7a. It "conclude[d] that the court erred finding this case to be 'exceptional' under 35 U.S.C. § 285." Pet. App. 12a. It reasoned that it had "repeatedly identified as 'exceptional' those cases involving 'inequitable conduct before the [Patent Office]; litigation misconduct; vexatious, unjustified, and otherwise bad faith litigation; a frivolous suit or willful infringement.'" Pet. App. 8a (citations omitted). It found that the district court's ruling of exceptionality "due to Abbott's bad-faith conduct which led to a holding of equitable estoppel" amounted to an "expansive reading of § 285." *Id.*

Asserting that it had never "upheld a finding of exceptionality based on a patentee's bad-faith business conduct toward an accused infringer prior to litigation," it declined "to expand the scope of the statutory term 'exceptional' in that manner." Pet. App. 9a. The court of appeals ignored the fact that it was, indeed, that "business conduct" that led directly to the lawsuit. It found that because Abbott's suit was not frivolous, it could not be "exceptional"

on the basis of bad faith, notwithstanding that "bad faith" and "frivolous suit" are ***separate*** grounds for "exceptionality."[2]

REASONS FOR GRANTING THE PETITION

This petition presents an important question of statutory interpretation that relates to the district court's ability in its discretion to punish misconduct, prevent injustice, and to make whole the party subjected to the bad-faith pre-litigation conduct. The court of appeals' new bright-line definition of "exceptional case" limits the district courts' exercise of discretion provided in the broad terms of § 285 as explained in the statutory history. That decision undermines the words of the statute, the clear legislative history, and decades of interpretation by the federal courts, all of which place the determination of "exceptionality" in the discretion of the district court on a case-by-case basis.

This Court has cautioned the court of appeals against too strongly favoring the clarity of new "bright-line" rules in nettlesome patent questions where Congressional intent and long-standing controlling precedent command that the question be left to the discretion of the district court.[3]

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2. Similarly, in *McNeil*, 337 F.3d at 1372, the court of appeals reversed an award of attorney fees based on the patentee's pre-litigation misconduct in procuring patents because "[w]e have not previously held [a patentee] liable for attorney fees . . . in the absence of clear and convincing evidence of inequitable conduct [before the PTO] or misconduct during litigation. We decline Perrigo's invitation to do so on these facts."

3. For example, in *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 730 (2002), the court of appeals

(Cont'd)

The court of appeals' decision also is inconsistent with the decisions interpreting the attorney fee shifting provisions in other areas of intellectual property, such as trademark, which as this Court has explained, is closely related to the patent attorney fee provision.

1. *The statutory provision and its legislative history provide district courts with discretion to determine if a patent case is "exceptional" and thereby warrants an award of attorney fees.* Section 285 provides that "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." "Exceptional case" is not further defined by Congress in the statute. Thus, the statute leaves the district court to determine in its discretion "exceptionality" and the subsequent awarding of attorney fees based on a case-by-case analysis of the losing party's misconduct.

The legislative history makes plain that "exceptionality" is to be determined by the district court — the court that has the opportunity to hear the evidence of the misconduct. The 1946 Patent Act added a punitive fee compensation provision to the patent law for the first time. Patent Rights – Protection, S. Rep. No. 79-1503 (June 14, 1946), *reprinted*

(Cont'd)
concluded that the flexible-bar rule for determining when prosecution history estoppel foreclosed a patentee's claim of equivalents "should be overruled because this case-by-case approach has proved unworkable." The court of appeals believed that its new complete-bar rule "would promote certainty in the determination of infringement cases." *Id.* This Court reversed despite acknowledging that the new "bright-line rule . . . would have provided more certainty in determining when estoppel applies." *Id.* at 739. It held "that the doctrine of equivalents and the rule of prosecution history estoppel are settled law" and, therefore, "[t]he responsibility for changing them rests with Congress." *Id.*

in 1946 U.S.C.C.A.N. 1386-87; compare Patent Rights – Protection, ch. 726, Pub. L. No. 79-587 (Aug. 1, 1946), *reprinted in* 1946 U.S.C.C.A.N. 744, with 35 U.S.C. § 70 (1929). Then 35 U.S.C. § 70 provided that "[t]he court may in its discretion award reasonable attorney's fees to the prevailing party upon the entry of judgment on any patent case." Patent Rights – Protection, ch. 726, Pub. L. No. 79-587 (Aug. 1, 1946), *reprinted in* 1946 U.S.C.C.A.N. 744; 35 U.S.C. § 70 (1951). When the attorney fee provision was codified in its current form in the 1952 Act, the term "in exceptional cases" was substituted for "in its discretion." 35 U.S.C. § 285 (1954). The Revised Note states, however, that § 285 "is substantially the same as the corresponding provision in R.S. 4921 [the earlier 1946 provision]; 'in exceptional cases' has been added as expressing the intention of the present statute as shown by its legislative history and as interpreted by the courts." 35 U.S.C. § 285, Revision Note, *reprinted in* 1952 U.S.C.C.A.N. 2403, 2423.

The 1946 Note of the Senate Committee on Patents explains that "the provision relating to attorney's fees is made discretionary with the court." Patent Rights – Protection, S. Rep. No. 79-1503 (June 14, 1946), *reprinted in* 1946 U.S.C.C.A.N. 1387. The Committee explained that

> the discretion given the court in this respect . . . will discourage infringement of a patent by anyone thinking that all he would be required to pay if he loses the suit would be a royalty. The provision is also made general so as to enable the court to prevent a gross injustice to an alleged infringer.

Id. Thus, the substitution of "in exceptional cases" for "in its discretion" in 1952 did not in any way limit the

discretion of the district court to determine "exceptionality" on a case-by-case basis.

Moreover, since the compensatory and punitive attorney fee provision entered the patent law in 1946, federal courts have held that it is to be implemented at the discretion of the trial court. In *Rohm & Haas Co.* v. *Crystal Chem. Co.*, 736 F.2d 688, 691 (Fed Cir. 1984), the court of appeals explained that "[s]ubsequent to the 1946 amendments, attorney fee awards were granted by the courts, in their discretion, primarily upon findings of extraordinary circumstances." Despite the fact that "the Patent Act of 1952, [which] codified the attorney fee provision in 35 U.S.C. § 285, . . . omits explicit reference to the court's discretion . . . [c]ases decided under § 285 have noted that 'the substitution of the phrase "in exceptional cases" has not done away with the discretionary feature.'" *Id.* (quoting *Hoge Warren Zimmermann Co.* v. *Nourse & Co.*, 293 F.2d 779, 783 (6th Cir. 1961)).[4]

At least one early case decided the specific question at issue here, determining that it is within the discretion of a district court to award attorney fees for pre-litigation misconduct. In *Brennan* v. *Hawley Prods. Co.*, 98 F. Supp. 369, 370 (N.D. Ill. 1951), the court barred an action for patent infringement because of laches and the defendant received an allowance of attorney fees. The trial court's laches decision

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4. *See also L.A. Gear, Inc.* v. *Thom McAn Shoe Co.*, 988 F.2d 1117, 1128 (Fed. Cir. 1993) (remanded for a determination of whether to award attorney fees to patentee because "[t]he trial judge is in the best position to weigh the factors 'that may contribute to a fair allocation of the burdens of litigation as between winner and loser,' in view of the entirety of the litigation circumstances") (citation omitted).

was affirmed by the court of appeals and certiorari was denied by this Court. *Id.* The defendant sought an allowance of fees for legal services rendered on appeal. *Id.* The court granted the requested attorney fees because "the record shows not only a long delay on the part of the plaintiff in instituting litigation on his claims of infringement, but also such a change in the condition of the defendant that it would be inequitable to allow plaintiff to enforce his claim for infringement." *Id.* The court explained that making such an award was "'in its discretion' . . . where one party has been guilty of some inequitable or unconscionable conduct." *Id.* (citation omitted). That the bad-faith laches misconduct was "pre-litigation" was of no consequence.

2. *The court of appeals ignored that the statutory provision and its legislative history afford the district courts with discretion to determine "exceptionality."* The court of appeals said nothing about the Congressional intent that attorney fees be awarded at the discretion of the district court.

Instead, the court of appeals cited its own precedent for the limiting proposition that "[w]e have repeatedly identified as 'exceptional' those cases involving 'inequitable conduct before the [Patent Office]; litigation misconduct; vexatious, unjustified, and otherwise bad faith litigation; a frivolous suit or willful infringement." Pet. App. 8a. Accordingly, it concluded "that Abbott's 'equitable estoppel' conduct was not an appropriate basis for awarding attorney fees under § 285 and that the district court's reliance on that ground was legal error." Pet. App. 9a.

The court of appeals did not even explain why awarding attorney fees has often been deemed appropriate in other types of pre-litigation conduct, such as inequitable conduct or willful infringement.

None of the cases relied on by the court of appeals as support for its new "bright-line" rule considered whether pre-litigation misconduct may be a basis for awarding attorney fees. In *Cambridge Prods., Ltd.* v. *Penn Nutrients, Inc.*, 962 F.2d 1048, 1051 (Fed. Cir. 1992), the prevailing alleged infringer was not entitled to attorney fees because its "bare assertion in its initial brief of entitlement under § 285 is not accompanied by any attempt at proving that this case is exceptional." In *Hoffmann-La Roche Inc.* v. *Invamed Inc.*, 213 F.3d 1359, 1365 (Fed. Cir. 2000), the court of appeals affirmed the district court's finding that the patentee "made a reasonable pre-filing inquiry" and, therefore, had not brought a frivolous suit. In *Brasseler, U.S.A. I, L.P.* v. *Stryker Sales Corp.*, 267 F.3d 1370 (Fed. Cir. 2001), the court of appeals affirmed an award of attorney fees where the patentee had engaged in inequitable conduct before the PTO. In *Yarway Corp.* v. *Eur-Control USA, Inc.*, 775 F.2d 268, 277 (Fed. Cir. 1985), the court of appeals reversed the district court's erroneous holding that alleged infringers had to pay the patentee's attorney fees because they "acted in bad faith by attempting to invent around the patent which they had licensed." The court of appeals reiterated that "the incentive to 'design around' patents is a positive result of the patent system." In other words, there was no misconduct at all.

Other decisions of the court of appeals make plain that, until recently, there was no such "bright-line" rule. In *Cambridge Prods.*, 962 F.2d at 1050-51, and *Brasseler*, 267 F.3d at 1380 (emphasis added), it stated that "[i]n the case of awards to prevailing accused infringers . . . 'exceptional cases' ***are normally those*** of bad faith litigation or those involving fraud or inequitable conduct by the patentee in procuring the patent." In *Hoffmann-La Roche*, 213 F.3d at 1365 (emphasis added; citation omitted), it stated

that "'***[a]mong the types of conduct*** which can form a basis for finding a case exceptional are willful infringement, inequitable conduct before the P.T.O., misconduct during litigation, vexatious or unjustified litigation, and frivolous suit.'"

Moreover, unlike this case, the cases relied on by the court of appeals frequently start their analysis with an acknowledgement that "[t]he award of attorney fees under § 285 is within the discretion of the court." *Cambridge Prods.*, 962 F.2d at 1050; *Yarway Corp.*, 775 F.2d at 277 (Section 285 "provide[s] the authority for the district court to act under its discretion" as long as "the exercise of discretion not be in conflict with the policies of the Patent Act").

3. *The court of appeals reformulated the district court's discretion to award attorney fees by instituting its new "bright-line" rule as the "proper legal standard under § 285" and reviewing* de novo *the district court's application of it.* The court of appeals' decision interferes with the district court's exercise of discretion by combining its new "bright-line" rule to its previous statements that it must review the legal application of § 285 *de novo*. Specifically, the court of appeals refused to consider bad-faith pre-litigation conduct as a basis for attorney fees. Thus, the court of appeals has changed the first step in its standard of review — it must "review *de novo* whether the [district] court applied the proper legal standard under § 285" — by *sua sponte* eliminating an entire class of conduct from the analysis. Pet. App. 5a. As a practical matter, the court of appeals has given itself *de novo* authority to determine whether the district court followed its new "bright-line" rule.

Here, by reviewing the application of its new rule *de novo*, the court of appeals determined that the district court committed "legal error." Pet. App. 9a. In doing so, the court of appeals never reached the real issues of whether the district court's factual findings on which it based a conclusion that Abbott's estoppel misconduct rendered the case "exceptional" were clear error or whether the district court's award of attorney fees based on its factual findings was an abuse of discretion. By adopting this legal standard that it reviews *de novo*, the court of appeals has given itself a vehicle with which to substitute its own judgment regarding the award of attorney fees for that of district courts — which it did in this case.

4. *Federal district courts exercise their discretion to determine whether a trademark case is "exceptional" and thereby warrants an award of attorney fees; instances of pre-litigation misconduct are considered in determining the "exceptionality" of trademark cases.* Like the Patent Act, the Lanham Act provides that "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party" in a trademark action. 15 U.S.C. § 1117(a). This Court has recognized that the fee shifting provision in the patent law is closely related to that in trademark. *Fogerty* v. *Fantasy, Inc.*, 510 U.S. 517, 525 n.12 (1994). Like the patent provision, the determination of an "exceptional" case is left to the district court's discretion. *Aromatique, Inc.* v. *Gold Seal, Inc.*, 28 F.3d 863, 876 (8th Cir. 1994). Federal courts "have defined the characteristics of exceptional cases with adjectives suggesting egregious conduct by a party," *e.g.*, "groundless, unreasonable, vexatious, or pursued in bad faith." *Id.* at 877.

Such conduct is not limited to specifically identified circumstances, but rather is "one in which one party's

behavior went beyond the pale of acceptable conduct." *Id.* Pre-litigation misconduct may lead to a finding of exceptionality. In *Aromatique*, the court of appeals reversed a holding of trademark infringement and awarded attorney fees to the alleged infringer because the plaintiff, among other things, twice wrote the alleged infringer prior to litigation alleging infringement and falsely asserting that the plaintiff's trade dress was federally registered. 28 F.3d at 878. The court of appeals held that "[t]his record compels the conclusion that [the alleged infringer] has shown that [the plaintiff's] conduct was exceptional within the meaning of Section 35 of the Lanham Act." *Id.* at 879.

5. *The court of appeals' decision is inconsistent with its own rule; "bad faith" is different from "frivolous suit" or "vexatious litigation."* The court of appeals' bright-line rule identifies, in part, "litigation misconduct; vexatious, unjustified, and otherwise ***bad faith*** litigation; [and] a frivolous suit" as conduct that "repeatedly" rendered a case "exceptional." Pet. App. 8a (emphasis added). The court of appeals' bright-line rule conflates the rule itself by making "bad faith" ***mean the same thing as*** "misconduct during litigation," "frivolous suit" and "vexatious litigation." For example, the court of appeals states that "[a]lthough a lawsuit pursued in bad faith is a sufficient basis for imposing attorney fees under § 285, such bad faith requires not misleading pre-litigation conduct, but vexatious, unjustified, or frivolous litigation." Pet App. 10a. This ignores that the plain meaning of otherwise bad-faith conduct encompasses more than litigation misconduct or bringing a frivolous suit. It also is contradicted by the court of appeals' analysis of whether Abbott's suit was frivolous in which it acknowledges that the bad faith equitable estoppel events are separate and apart from a consideration of whether the suit was frivolous.

Pet. App. 10a-11a ("The record, however, does not support the district court's finding that Abbott maintained its infringement counterclaim in bad faith. Even if Abbott had knowledge of the events that would ultimately lead to a holding of equitable estoppel, its litigation position was not frivolous or baseless.").

The plain words of the statute and the legislative history show that "bad faith" should be interpreted to mean all dealings between the parties that relates to the litigation. Here, the court of appeals did not reverse a single one of the district court's numerous fact findings in support of its conclusion that Abbott's "equitable estoppel" business conduct was in bad faith and that Abbott provided no evidence of good faith. Rather, the court of appeals legislated a change to the statute to prevent recovery of attorney fees in cases of bad-faith pre-litigation conduct.

CONCLUSION

The petition for a writ of certiorari should be granted. Congress, in 35 U.S.C. § 285, gave discretionary authority to the district courts to award attorney fees in "exceptional" patent cases to prevent a gross injustice to an abused party. The court of appeals, however, through its new bright-line rule defining the legal standard of § 285 and *de novo* review of the district courts' application of it, has removed the discretion of the district court and decided the specific circumstances under which attorney fees may be awarded. Its bright-line rule also has undone the distinction between "bad-faith" misconduct and bringing a "frivolous suit." Here, this has resulted in a fundamentally unfair result. The district court, which was in the best position to determine if respondent's conduct rendered the case "exceptional" after adjudicating years of litigation and a four-month trial, exercised its discretion to award fees to petitioners to compensate them for their substantial and unjustified loss incurred in successfully defending this suit. That compensation has now been taken from them because of second-guessing by the court of appeals.

Respectfully submitted,

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APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT FILED AUGUST 7, 2003

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

03-1067

FOREST LABORATORIES, INC. AND ONY, INC.,

Plaintiffs-Appellees,

v.

ABBOTT LABORATORIES,

Defendant-Appellant,

and

TOKYO TANABE COMPANY, LTD.,

Defendant.

DECIDED: August 7, 2003

Before LOURIE, RADER, and DYK, *Circuit Judges.*

LOURIE, *Circuit Judge.*

Abbott Laboratories appeals from the decision of the United States District Court for the Western District of New York awarding attorney fees and expenses to ONY, Inc.

and Forest Laboratories, Inc. based on Abbott's conduct that led to a holding of equitable estoppel. *Forest Labs., Inc. v. Abbott Labs.*, No. 96-CV-159A (W.D.N.Y. Sept. 4, 2001) ("*Forest IV*"). Because we conclude that the court erred in finding this case to be "exceptional" under 35 U.S.C. § 285, we reverse.

BACKGROUND

Tokyo Tanabe Company, Ltd. owns U.S. Patents 4,338,301 and 4,397,839, which are directed to a lung surfactant composition for treating respiratory distress syndrome in premature babies. Pursuant to an exclusive license of the '301 and '839 patents, Abbott developed a commercial product known as Survanta® in the 1980s. At about the same time, ONY developed its own product for treating neonatal respiratory distress syndrome called Calf Lung Surfactant Extract ("CLSE"). In June 1991, ONY entered into an agreement with Forest for Forest to further develop and market CLSE under the trade name Infasurf®.

From 1983 until 1991, Abbott and ONY maintained contact regarding the development of CLSE. Abbott met with ONY in November 1983 to discuss the development, composition, and testing of CLSE, and later informed ONY that it had opted to develop the Tanabe product instead of CLSE because the Tanabe product had patent protection. In April 1984, at Abbott's request, ONY submitted a memorandum of invention to Abbott disclosing "everything known about CLSE" for Abbott to conduct a patentability search. Upon completion of the search, Abbott informed ONY that CLSE was likely not patentable in light of two "pertinent

references," but did not mention the '301 and '839 patents; nonetheless, Abbott encouraged ONY that it "look[ed] forward to working with [ONY] in the future." In April 1986, Abbott again met with ONY to discuss the possibility of joint development of CLSE and suggested that "some future collaboration" might still be possible. Abbott continued to monitor the development of CLSE until 1991, while internally expressing concern that ONY might receive FDA approval for CLSE before Abbott could do so for Survanta®.

In July 1991, Abbott received both FDA approval and orphan drug status (providing seven years' market exclusivity) for Survanta®, which it then proceeded to market. Several years later, Abbott informed ONY and Forest that it had reason to believe that Infasurf® would infringe the '301 and '839 patents if it were to be marketed. Nonetheless, in March 1995, ONY filed a new drug application for approval to market Infasurf®. The FDA then notified ONY that Infasurf® was the "same drug" as Survanta® under the Orphan Drug Act, 21 U.S.C. §§ 360aa-360dd (1994), and that it therefore could not be approved for sale until Abbott's period of exclusivity expired in July 1998.

In light of Abbott's June 1994 letter claiming infringement and the FDA's notification that Infasurf® and Survanta® were the "same drug," ONY and Forest sued Abbott and Tanabe in the U.S. District Court for the Western District of New York, seeking a declaratory judgment of noninfringement and invalidity of the '301 and '839 patents. Abbott and Tanabe counterclaimed for infringement. A jury found both patents infringed and not invalid and, in an advisory verdict, rejected ONY and Forest's defense of

equitable estoppel. The district court, however, granted ONY and Forest a judgment of noninfringement as a matter of law ("JMOL") on the ground that Abbott and Tanabe had failed to present any evidence at trial to show that CLSE met the water content limitations of the patents in suit either literally or under the doctrine of equivalents. *Forest Labs., Inc. v. Abbott Labs.*, No. 96-CV-159A, 1999 U.S. Dist. LEXIS 23217, at *20-21 (W.D.N.Y. June 23, 1999) ("*Forest I*"). In a separate opinion, the court also ruled that Abbott, and Tanabe by imputation, was equitably estopped from asserting infringement of the '301 and '839 patents against ONY and Forest because: (1) Abbott, in bad faith, misled ONY and Forest to believe that it would not assert infringement by encouraging their development of Infasurf® and by neglecting its duty to inform them of any possible infringement; (2) ONY and Forest reasonably relied on Abbott's misleading conduct; and (3) ONY and Forest would suffer economic and evidentiary prejudice if Abbott were permitted to proceed with its infringement counterclaim. *Forest Labs., Inc. v. Abbott Labs.*, No. 96-CV-159A, 1999 U.S. Dist. LEXIS 23215, at *25-26 (W.D.N.Y. June 23, 1999) ("*Forest II*"). On appeal, we affirmed the JMOL of noninfringement and, having done so, declined to consider the equitable estoppel issue. *Forest Labs., Inc. v. Abbott Labs.*, 239 F.3d 1305, 1314 (Fed. Cir. 2001) ("*Forest III*").

The district court subsequently granted ONY and Forest's motion for attorney fees and expenses against Abbott, but not Tanabe. The court found the case to be "exceptional" under 35 U.S.C. § 285 because Abbott, in bad faith, encouraged ONY to develop CLSE, disregarded its duty to advise ONY and Forest of possible infringement, and pursued

its infringement counterclaim with a "reckless disregard for the facts in an attempt to prevent Infasurf from reaching the market." *Forest IV*, slip op. at 12. In so finding, the court rejected Abbott's argument that fees could not be awarded for bad-faith conduct that occurred prior to litigation and held that, in any event, Abbott had acted in bad faith during litigation by bringing suit with knowledge of its prior bad-faith conduct toward ONY and Forest. *Id.* at 11. Having found the case to be exceptional, the court then chose to exercise its discretion and award attorney fees in order to avoid a "gross injustice" and to deter patentees from similar bad-faith conduct in the future. *Id.* at 15. Upon the parties' stipulation as to the amount of any fee award, the court entered an award against Abbott of $6.5 million in attorney fees and expenses. *Forest Labs., Inc. v. Abbott Labs.*, No. 96-CV-159A (W.D.N.Y. Sept. 30, 2002).

Abbott timely appealed the fee award to this court. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

A determination whether to award attorney fees under 35 U.S.C. § 285 involves a two-step process. First, a district court must determine whether the prevailing party has proved by clear and convincing evidence, *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 669 (Fed. Cir. 2000), that the case is "exceptional." 35 U.S.C. § 285 (2000); *Cybor Corp. v. FAS Techs.*, 138 F.3d 1448, 1460 (Fed. Cir. 1998) (en banc). We review *de novo* whether the court applied the proper legal standard under § 285, and we review the court's factual findings, including whether the case is exceptional, for clear

error. *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1378 (Fed. Cir. 2001). A finding is clearly erroneous when, despite some supporting evidence, "the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 395 (1948). Second, if the district court finds the case to be exceptional, it must then determine whether an award of attorney fees is appropriate. *Cybor Corp.*, 138 F.3d at 1460. We review that determination for an abuse of discretion. *Id.* A district court abuses its discretion when "its decision is based on clearly erroneous findings of fact, is based on erroneous interpretations of the law, or is clearly unreasonable, arbitrary or fanciful." *Id.* (citation omitted).

On appeal, Abbott first argues that the district court improperly found this case to be exceptional. Abbott contends that the court's underlying determination of equitable estoppel was clear error and, in any event, was based on only a preponderance of the evidence, whereas a finding that a case is exceptional under § 285 requires clear and convincing evidence. Abbott also argues that its private pre-litigation conduct was an inappropriate ground on which to base a finding of exceptionality and that it did not engage in bad-faith conduct during litigation because its legal position was neither frivolous nor baseless. Abbott further maintains that the district court's decision to award attorney fees was an abuse of discretion in light of the court's erroneous, or at least debatable, holding of equitable estoppel; the absence of any allegation of litigation misconduct; and the jury's advisory rejection of ONY and Forest's equitable estoppel defense. Finally, Abbott argues that the fee award serves

neither of the intended purposes of § 285 in that it does not deter unwarranted infringement claims or prevent injustice to those falsely accused of infringement.

ONY and Forest respond that the district court properly found that Abbott's bad-faith conduct, *viz.*, its failure to raise the issue of infringement with ONY and Forest between 1983 and 1994, while encouraging the development of Infasurf® as an alternative until it received FDA approval for Survanta®, makes this case exceptional. They point out that the court did not need to find by clear and convincing evidence that the elements of an equitable estoppel defense were proved, but only that this case was exceptional. ONY and Forest also maintain that a finding of exceptionality was appropriate because Abbott should have recognized that its pre-litigation conduct precluded it from bringing suit. They further argue that Abbott's bad-faith conduct continued during litigation because Abbott persisted with its counterclaim of infringement in complete disregard of its history of dealings with ONY and Forest. In addition, ONY and Forest contend that Abbott's failure to offer any evidence of infringement with respect to the water content limitations of the asserted patents renders this case exceptional. Finally, ONY and Forest argue that the district court did not abuse its discretion in awarding fees in this case because, as the court explained, the holding of equitable estoppel alone did not make ONY and Forest whole, and not awarding fees could encourage other patentees that have engaged in similar bad-faith conduct to bring unwarranted infringement claims.

We agree with Abbott that the district court erred in awarding attorney fees to ONY and Forest. Section 285

provides that a "court in exceptional cases may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285 (2000). We have repeatedly identified as "exceptional" those cases involving "inequitable conduct before the [Patent Office]; litigation misconduct; vexatious, unjustified, and otherwise bad faith litigation; a frivolous suit or willful infringement." *Brasseler*, 267 F.3d at 1380 (citation omitted); *e.g.*, *Hoffman-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359, 1365 (Fed. Cir. 2000). None of those circumstances is present here, yet the district court found that this case was exceptional due to Abbott's bad-faith conduct which led to a holding of equitable estoppel. *Forest IV*, slip op. at 9-11. We disagree with the court's expansive reading of § 285.

In interpreting § 285, we have been mindful of the limited circumstances in which an award of attorney fees is appropriate. *See Mach. Corp. of Am. v. Gullfiber AB*, 774 F.2d 467, 472 (Fed. Cir. 1985). The Senate Report accompanying § 285's predecessor statute, which is applicable to the present statute as well, states that "'[i]t is not contemplated that the recovery of attorney's fees will become an ordinary thing in patent suits.'" *Rohm & Haas Co. v. Crystal Chem. Co.*, 736 F.2d 688, 690-91 (Fed. Cir. 1984) (quoting S. Rep. No. 79-1503 (1946)). Indeed, we have recognized that § 285 is an exception to the American Rule and a change to the pre-1946 practice of not awarding attorney fees based upon equitable considerations in patent cases. *Id.* at 690. In the context of fee awards to prevailing accused infringers, we have observed that § 285 is limited to circumstances in which it is necessary to prevent "a gross injustice" to the accused infringer, *see Mach. Corp.*, 774 F.2d at 472 (quoting S. Rep. No. 79-1503 (1946)), and have upheld

findings of exceptionality to prevent such an injustice only when the patentee has procured its patent in bad faith (*i.e.*, committed inequitable conduct before the Patent Office) or has litigated its claim of infringement in bad faith. *See Cambridge Prods., Ltd. v. Penn Nutrients, Inc.*, 962 F.2d 1048, 1050-51 (Fed. Cir. 1992); *Mach. Corp.*, 774 F.2d at 472.

We have not, however, upheld a finding of exceptionality based on a patentee's bad-faith business conduct toward an accused infringer prior to litigation, and we decline to expand the scope of the statutory term "exceptional" in that manner. *Cf. Yarway Corp. v. Eur-Control USA, Inc.*, 775 F.2d 268, 277-78 (Fed. Cir. 1985) (reversing a finding of exceptionality premised on an accused infringer's bad-faith conduct of attempting to design around a patent in order to circumvent a license agreement). Equitable estoppel may be imposed in a patent case when a patentee induces another party to believe that it will not sue that party for infringement. *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1042 (Fed. Cir. 1992) (en banc). Reliance by the other party as well as prejudice are required in order to estop the patentee from later suing. *Id.* at 1042-43. The consequence of estoppel is loss of the cause of action, *id.* at 1028, and we have not extended the consequences to include attorney fees under the rubric of exceptional case. Such business conduct, even though sufficiently relied upon and prejudicial to lead to estoppel, does not make any subsequent lawsuit exceptional. Accordingly, we conclude that Abbot's "equitable estoppel" conduct was not an appropriate basis for awarding attorney fees under § 285 and that the district court's reliance on that ground was legal error.

We also agree with Abbott that the district court clearly erred in finding that Abbott engaged in bad-faith litigation. Although a lawsuit pursued in bad faith is a sufficient basis for imposing attorney fees under § 285, such bad faith requires not misleading pre-litigation conduct, but vexatious, unjustified, or frivolous litigation. *See, e.g.*, *Aptix Corp. v. Quickturn Design Sys., Inc.*, 269 F.3d 1369, 1375 (Fed. Cir. 2001) (affirming an award of attorney fees under § 285 for the "extreme litigation misconduct" of falsifying evidence); *Eltech Sys. Corp. v. PPG Indus., Inc.*, 903 F.2d 805, 810-11 (Fed. Cir. 1990) (affirming an award of attorney fees under § 285 for pursuing a baseless claim of infringement). There is no suggestion that Abbott engaged in vexatious litigation tactics; the pertinent inquiry is thus whether Abbott knew or should have known that it would be estopped from asserting the '301 and '839 patents against ONY and Forest, but pursued its infringement counterclaim anyway. *See Haynes Int'l Inc. v. Jessop Steel Co.*, 8 F.3d 1573, 1579 (Fed. Cir. 1993) ("A frivolous infringement suit is one which the patentee knew or, on reasonable investigation, should have known, was baseless."), *reh'g granted on other grounds*, 15 F.3d 1076 (1994). The district court answered that question in the affirmative, observing that Abbott "obviously knew of its own bad faith conduct prior to the commencement of the lawsuit," *Forest IV*, slip op. at 11, and nevertheless pursued its infringement counterclaim with a "reckless disregard" for the facts of the case and the validity of ONY and Forest's equitable estoppel defense, *id.* at 12.

The record, however, does not support the district court's findings that Abbott maintained its infringement counterclaim in bad faith. Even if Abbott had knowledge of the events

that would ultimately lead to a holding of equitable estoppel, its litigation position was not frivolous or baseless. Indeed, based on the facts of this case, it was far from a foregone conclusion that ONY and Forest would be able to establish their equitable estoppel defense successfully. Abbott never expressly communicated to Forest or ONY that it did not intend to enforce its patents; instead, the district court had to infer a misleading statement from Abbot's conduct and did so only after finding that Abbott had a duty to advise ONY and Forest of any possible infringement when it provided ONY with a patentability opinion. *See ABB Robotics, Inc. v. GMFanuc Robotics Corp.*, 52 F.3d 1062, 1063 (Fed. Cir. 1995); *see also A.C. Aukerman Co.*, 960 F.2d at 1041 ("[E]quitable estoppel is not limited to a particular factual situation nor subject to resolution by simple or hard and fast rules."). Although the equitable estoppel issue is not before us, we note that it was never finally resolved, for we declined to consider Abbott's appeal of that issue when we affirmed the JMOL of noninfringement. *Forest III*, 239 F.3d at 1314. Once it had been concluded that ONY and Forest were not infringing the Abbott-Tanabe patents, whether Abbott would be estopped from enforcing those patents against ONY and Forest became moot. In any event, we cannot even say with confidence that the equitable estoppel determination would have been affirmed had we reached the issue on appeal. Moreover, the district court's denial of ONY and Forest's motion for JMOL at the close of the evidence and the jury's advisory verdict of no equitable estoppel suggest that Abbott's position was not baseless. In light of these considerations, we conclude that Abbott's litigation position with respect to the equitable estoppel issue cannot be characterized as clearly and convincingly

vexatious, unjustified, or frivolous. Accordingly, the district court's finding that Abbott engaged in bad-faith litigation was clearly erroneous.

Finally, we reject ONY and Forest's argument that an award of attorney fees is appropriate because Abbott failed to offer any evidence of infringement regarding the water content limitations of the asserted patents. Although Abbott ultimately lost its infringement counterclaim on that ground, *id.*, we cannot say that such a lack of proof is clear and convincing evidence that Abbott, acting in bad faith, asserted a baseless or frivolous counterclaim of infringement. Indeed, the jury's finding of infringement suggests otherwise. Moreover, the district court expressly disclaimed reliance on Abbott's failure to prove infringement as a basis for imposing attorney fees, noting that Abbott presented "plausible yet untenable arguments regarding claim construction and the doctrine of equivalents." *Forest IV*, slip op. at 16-17. Thus, even if Abbott's lack of evidence of infringement could support a findings exceptionality under § 285, the district court did not abuse its discretion in choosing not to award fees on that ground.

CONCLUSION

For the foregoing reasons, we conclude that the district court erred in finding this case to be "exceptional" under 35 U.S.C. § 285 based on Abbott's pre-litigation conduct toward ONY and Forest. Accordingly, the decision of the district court is

REVERSED.

APPENDIX B — DECISION AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF NEW YORK FILED SEPTEMBER 30, 2002

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

96-CV-159A

FOREST LABORATORIES, INC. and ONY, INC.,

Plaintiffs,

v.

ABBOTT LABORATORIES and
TOKYO TANABE COMPANY, LTD.,

Defendants.

DECISION AND ORDER

On September 4, 2001, this Court issued a Decision and Order in this case granting the motion of plaintiffs Forest Laboratories, Inc. ("Forest") and ONY, Inc. ("ONY") for attorneys' fees, pursuant to 35 U.S.C. § 285, against defendant Abbott Laboratories ("Abbott"). The Court denied the motion with respect to defendant Tokyo Tanabe Company, Ltd. The Court also appointed Michael R. McGee, Esq., pursuant to Rule 53 of the Federal Rules of Civil Procedure, as Special Master to hear and report on the reasonable amount of attorneys' fees and expenses that Abbott should pay,

defendants' objections to the plaintiffs' bill of costs, the amount of prejudgment and/or post-judgment interest and any other related issues.

On September 6, 2002, the Special Master filed a Report and Recommendation, informing the Court that the parties had entered into Joint Stipulation Regarding the Amount of Fees and Expenses ("Joint Stipulation"). The Special Master finds that the Joint Stipulation is a reasonable resolution of all the issues referred to the Special Master by the Court's September 4, 2001 Decision and Order.

There being no timely objections filed to the Special Master's Report and Recommendation, the Court hereby adopts the Report and Recommendation in all respects, pursuant to Rule 53(e)(2). Pursuant to Rules 54(d)(2)(C) and 58 of the Federal Rules of Civil Procedure, the Court hereby orders the Clerk of Court to enter judgment in favor of Forest and ONY consistent with the Court's September 4, 2001 Decision and Order, this Decision and Order, the Special Master's Report and Recommendation and the Joint Stipulation, and to take all steps necessary to close the case.

The Court commends the Special Master on assisting the parties in reaching an agreeable resolution to these complex issues and thanks him for a job well done.

IT IS SO ORDERED.

s/ Richard J. Arcara
HONORABLE RICHARD J. ARCARA
UNITED STATES DISTRICT COURT

Dated: September 30, 2002.

APPENDIX C — DECISION AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF NEW YORK FILED SEPTEMBER 4, 2001

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

96-CV-159A

FOREST LABORATORIES, INC. AND ONY, INC.,

Plaintiffs,

v.

ABBOTT LABORATORIES AND
TOKYO TANABE COMPANY, LTD.,

Defendants.

DECISION AND ORDER

INTRODUCTION

Currently before the Court is the motion of plaintiffs, Forest Laboratories, Inc. ("Forest") and ONY, Inc. ("ONY"), for an award of attorneys' fees and expenses, pursuant to 35 U.S.C. § 285, against defendants Abbott Laboratories ("Abbott") and Tokyo Tanabe Company, Ltd. ("Tokyo Tanabe").[1] By Order filed July 20, 1999, the Court ordered

1. Plaintiffs have also submitted a Bill of Costs pursuant to Local Rule 54, Rule 54(d) of the Federal Rules of Civil Procedure 54(d), and 28 U.S.C. § 1920. Defendants have filed objections to the Bill of Costs.

the parties to brief the issues of whether plaintiffs are entitled to attorneys' fees and expenses pursuant to § 285, and held in abeyance the issue of whether the amount of attorneys' fees and expenses requested by plaintiffs is reasonable. Oral argument on the issue of whether plaintiffs are entitled to attorneys' fees and expenses was held on July 19, 2001.

After reviewing the submissions of the parties and hearing argument from counsel, the Court grants plaintiffs' motion for attorneys' fees and expenses with regard to defendant Abbott, but denies the motion with regard to defendant Tokyo Tanabe.

BACKGROUND

Tokyo Tanabe is the assignee of U.S. Patents 4,338,301 and 4,397,839, which relate to a lung surfactant composition for treating Respiratory Distress Syndrome ("RDS") in premature babies. Abbott developed a commercial product known as "Survanta®" after receiving an exclusive U.S. license to these patents from Tokyo Tanabe. ONY developed a competing product for treating RDS, which it called "Infasurf®." ONY eventually entered into an agreement with Forest under which Forest would further develop and market Infasurf®. ONY and Abbott maintained collaborative contacts throughout the development of these products from 1983 until Abbott received FDA approval to market Survanta® in 1991, during which time Abbott never gave ONY any reason to believe that its Infasurf® product would infringe any patents of Abbott. In fact, Abbott performed a patentability search for ONY in 1984 and never mentioned the Tokyo Tanabe patents under which Abbott was exclusively licensed.

However, in 1994, Abbott informed ONY that it had reason to believe that Infasurf® might infringe the Tokyo Tanabe patents.

In 1996, ONY and Forest sued Abbott, seeking a declaratory judgment of non-infringement and patent invalidity. Abbott counterclaimed for infringement. After suit was brought, ONY and Forest added Tokyo Tanabe as a defendant, which also counterclaimed for infringement. ONY and Forest later raised the additional defense of equitable estoppel, alleging that Abbott had led ONY to believe that Abbott would not assert the Tokyo Tanabe patents against it.

A jury returned a verdict in favor of Abbott and Tokyo Tanabe on all issues except willfulness. The jury also returned an advisory verdict in favor of Abbott on the issue of equitable estoppel. ONY and Forest then moved for a post-trial judgment of equitable estoppel and judgment as a matter of law ("JMOL") of non-infringement. The Court, stating that it was not bound by the advisory verdict, applied equitable estoppel after concluding that Abbott had misled ONY into believing that it did not infringe the Tokyo Tanabe patents and that ONY had relied on Abbot's conduct and was prejudiced by it. *See Forest Labs. v. Abbott Labs.*, 1999 WL 33299123 (W.D.N.Y. Jun. 23, 1999) ("Equitable Estoppel Decision"). The Court also granted ONY's and Forest's motion for JMOL of non-infringement and its motion for a conditional new trial, because it found that Abbott and Tokyo Tanabe had failed to prove that CLSE ("Calf Lung Surfactant Extract," the "dry" form of Infasurf®) met the claim limitations requiring specific water content percentages. *See Forest Labs. v. Abbott Labs.*, 1999 WL 33290607

(W.D.N.Y. Jun. 23, 1999). Finally, the Court rejected defendant's claim of infringement under the doctrine of equivalents for lack of evidence of equivalence. *Id.*

Abbott and Tokyo Tanabe appealed the Court's judgment applying equitable estoppel and its grant of JMOL of non-infringement. The Federal Circuit Court of Appeals affirmed the Court's grant of JMOL of non-infringement, agreeing that there was no proof that CLSE, based on its dry weight, possessed the percentages of water claimed by the patents. *See Forest Labs. v. Abbott Labs.*, 239 F.3d 1305 (Fed. Cir. 2001).[2] Because it affirmed this Court decision on the basis of its grant of JMOL of non-infringement, the Federal Circuit did not decide the equitable estoppel issue.

DISCUSSION

A. *Law Regarding § 285*

Under 35 U.S.C. § 285, "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." The purpose of the statute is "'to compensate the prevailing party for its monetary outlays in the prosecution or defense of the suit.'" *Automated Business Cos. v. NEC Am., Inc.*, 202 F.3d 1353, 1355 (Fed. Cir. 2000) (quoting *Central Soya Co. v. Geo. A. Hormel & Co.*, 723 F.2d 1573, 1578 (Fed. Cir. 1983)). "In addition, § 285 serves as a deterrent to 'improper bringing of clearly unwarranted suits' for patent infringement." *Id.* (quoting *Mathis v. Spears*, 857 F.2d 749, 754 (Fed. Cir. 1988)).

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2. The Court hereby incorporates by reference, and assumes familiarity with, all of its prior decisions in this case. The Court also assumes familiarity with the Federal Circuit's decision.

Appendix C

Whether to award attorneys' fees under § 285 rests with the sound discretion of the trial court. *Modine Mfg. Co. v. Allen Group, Inc.*, 917 F.2d 538, 543 (Fed. Cir. 1990), *cert. denied*, 500 U.S. 918 (1991). Congress intended that courts use their discretion under § 285 sparingly as the statute is a departure from the usual "American rule" that counsel fees are not awarded to the prevailing party in an action at law. *See Victus Ltd. v. Collezione Europa U.S.A., Inc.*, 26 F. Supp. 2d 772, 787 (M.D.N.C. 1998) (citation omitted).

> Thus, the payment of attorney's fees for the victor is not to be regarded as a penalty for failure to win a patent infringement suit. *The exercise of discretion* in favor of such an allowance *should be bottomed upon* a finding of *unfairness or bad faith in the conduct of the losing party*, or some other equitable consideration of similar force, *which makes it grossly unjust that the winner of the particular lawsuit be left to bear the burden of his own counsel fees* which prevailing litigants normally bear.

Rohm & Haas Co. v. Crystal Chem. Co., 736 F.2d 688, 691 (Fed. Cir. 1984) (emphasis in original) (quoting *Park-In-Theaters, Inc. v. Perkins*, 190 F.2d 137, 142 (9th Cir. 1951)).

Deciding a motion for attorneys' fees under § 285 requires a two-step analysis. *J.P. Stevens Co. v. Lex Tex Ltd.*, 822 F.2d 1047, 1050 (Fed. Cir. 1987). The court "must determine whether the case is 'exceptional;' if it is, then it is within the court's discretion to award attorneys' fees to the prevailing party. It is only after a specific finding of

exceptional circumstances has been made that the discretion to award attorneys' fees can be exercised." *Id.* (citations omitted).

The determination that a case is "exceptional" is a factual one and should be made in light of the totality of the circumstances. *See Interspiro USA, Inc. v. Figgie Int'l Inc.*, 18 F.3d 927, 933 (Fed. Cir. 1994); *L.A. Gear, Inc. v. Thom McAn Shoe Co.*, 988 F.2d 1117, 1128 (Fed. Cir.), *cert. denied*, 510 U.S. 908 (1993). A prevailing party seeking an award of attorneys' fees has the burden of establishing the exceptional character of the case by clear and convincing evidence.[3] *See B. Braun Medical, Inc. v. Abbott Labs.*, 124 F.3d 1419, 1429 (Fed. Cir. 1997). For an alleged infringer to recover attorneys' fees under § 285, "[t]here must be some finding of unfairness, bad faith, or inequitable conduct on the part of the unsuccessful patentee." *Stevenson v. Sears, Roebuck & Co.*, 713 F.2d 705, 713 (Fed. Cir. 1983) (citations omitted); *see also Badalamenti v. Dunham's, Inc.*, 896 F.2d 1359, 1364-65 (Fed. Cir.), *cert. denied*, 498 U.S. 851 (1990); *Advance Transformer Co. v. Levinson*, 837 F.2d 1081, 1085

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3. Clear and convincing evidence is a more exacting sandard than proof by a preponderance of the evidence, but is not as high a standard as the burden of proof applied in criminal cases which is proof beyond a reasonable doubt. Clear and convincing proof leaves no substantial doubt in the fact finder's mind. It is proof that establishes in the fact finder's mind not only that the proposition at issue is probable, but also that it is highly probable. It is enough if the party with the burden of proof establishes its claim beyond any substantial doubt. It does not have to dispel every reasonable doubt. *See* Sand, Siffert, Loughlin & Reiss, *Modern Federal Jury Instructions*, Instruction No. 73-3.

(Fed. Cir. 1988). The alleged infringer must demonstrate evidence of either wrongful intent or gross negligence. *Machinery Corp. of Am. v. Gullfiber AB*, 774 F.2d 467, 473 (Fed. Cir. 1985).

Even if the case is found to be "exceptional," the court, in its discretion, may decline to award attorneys' fees. "After the district court determines that a case is exceptional there remains in every case its freedom to exercise its discretion informed by the court's familiarity with the matter in litigation and the interest of justice." *Gardco Mfg., Inc. v. Herst Lighting Co.*, 820 F.2d 1209, 1215 (Fed. Cir. 1987) (internal quotations and citations omitted).

> Even an exceptional case does not require in all circumstances the award of attorney fees. Many factors could affect this result. The trial judge is in the best position to weigh considerations such as the closeness of the case, tactics of counsel, the conduct of the parties, and any other factors that may contribute to a fair allocation of the burdens of litigation as between winner and looser.

S.C. Johnson & Son, Inc. v. Carter-Wallace, Inc., 781 F.2d 198, 201 (Fed. Cir. 1986).

B. *Application of Law to Facts*

Applying the above principles to the instant case, the Court finds that with respect to Abbott, ONY and Forest have shown by clear and convincing evidence that this is an "exceptional" case within the meaning of § 285, and that

they should be awarded their attorneys' fees and expenses. With respect to Tokyo Tanabe, however, the Court finds that this is not an "exceptional" case and therefore an award of attorneys' fees is not appropriate.

1. *Abbott*

As discussed in detail in the Court' Equitable Estoppel Decision, Abbott misled ONY and Forest into reasonably believing that Abbott did not intend to enforce the Tokyo Tanabe patents against them. This is not, as Abbott contends, a case involving mere silence or inaction on the part of the patentee. To the contrary, the evidence shows that between 1983 and 1994, Abbott was fully aware of ONY's and Forest's activities and that up until 1991, Abbott actively encouraged Dr. Edmund A. Egan, the president of ONY, in his efforts to develop CLSE. Such conduct created a duty on the part of Abbott to advise ONY and Forest about possible infringement of the Tokyo Tanabe patents, yet Abbott never mentioned infringement until June of 1994, eleven years after it first learned about CLSE.

The evidence adduced at trial shows that the reason Abbott kept encouraging ONY to develop CLSE, even though it was a possible competitor, was because Abbott wanted to keep its options open in the event Survanta®, the product that Abbott had developed based on the Tokyo Tanabe patents, was not approved by the FDA for commercial sale or did not work out for some other reason. In other words, Abbott was betting on two horses—if efforts to develop Survanta® failed, Abbott could return to ONY and CLSE. Once Abbott finally got FDA approval of Survanta®, however, it stopped stringing

Dr. Egan along, cut off all contact with him and eventually asserted an infringement claim against ONY and Forest. Such conduct amounts to bad faith on the part of Abbott and makes this an "exceptional" case for purposes of § 285.[4]

Abbott put forth no persuasive evidence at trial to contradict ONY's and Forest's evidence of its bad faith. Interestingly, three of the witnesses who would have been in the best position to provide such evidence, attorneys Donald Nickey and Margaret O'Brien, and Dr. Jack Gold, were listed as potential witnesses on Abbott's witness list but were never called to testify. Although the Court recognizes that the burden of proof on the issue of equitable estoppel was on ONY and Forest, once they put forth sufficient evidence to establish an equitable estoppel defense. It was up to Abbott to either rebut such evidence or run the risk of an adverse verdict. Abbott chose the latter option.

Abbott argues that the "bad faith" necessary for a finding of exceptional circumstances under § 285 is not the same "bad faith" necessary for purposes of equitable estoppel. In other words, according to Abbott, "bad faith" for purposes of § 285 must be bad faith in the conduct of the litigation of the lawsuit, not bad faith by a party prior to the lawsuit commencing. The Court finds this argument without merit.

Although it is true that cases awarding a prevailing accused infringer attorneys' fees have normally been those

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4. Although the Court's findings of fact regarding Abbot's bad faith contained in its Equitable Estoppel Decision were based on a preponderance of the evidence standard, the Court finds that the same evidence also supports a finding of bad faith by clear and convincing evidence.

involving bad faith litigation or fraud or inequitable conduct by the patentee in procuring the patent, Abbott has failed to cite, nor has the Court found, any cases prohibiting an award of attorneys' fees based on the bad faith conduct of the patentee prior to the lawsuit.

Moreover, even if bad faith in litigating the lawsuit is necessary for a case to be "exceptional," such bad faith is present here. Abbott obviously knew of its own bad faith conduct prior to the commencement of the lawsuit, yet persisted in bringing an infringement claim against Forest and ONY.

Particularly pertinent here is the case of *Nordek Corp. v. Garbe Ironworks, Inc.*, 1983 WL 223, 221 U.S.P.Q. 632 (N.D. Ill. April 25, 1983). In *Nordek*, the district court awarded the alleged infringer its attorneys' fees because the patentee persisted in the litigation in the fact of compelling laches and estoppel defenses. The patentee pursued the litigation even though it knew or should have known that the suit was barred by its own misleading conduct and foot dragging. The Court concluded that the patentee's behavior made the case exceptional:

> Prosecution of this lawsuit without investigation into possible laches and estoppel defenses was recklessness amounting to bad faith. Plaintiff's failure to change its course as defendants' evidence mounted is clear and convincing evidence of plaintiff's bad faith.

See also Encomp, Inc. v. L-com, Inc., 999 F. Supp. 264, 269-70 (D. Conn. 1998) (granting alleged infringer's motion

for attorneys' fees because the patentee's "suit was frivolously brought in that it failed to access [laches and equitable estoppel] defenses that would have essentially precluded its claims.").

Similarly, Abbott's conduct renders this case "exceptional." The evidence concerning ONY's and Forest's estoppel defense was in Abbott's own files and was well known by Abbott's own employees well before Abbott sent its first letter to ONY and Forest asserting infringement. Nevertheless, Abbott pursued its infringement claim with a reckless disregard for the facts in an attempt to prevent Infasurf® from reaching the market. Such disregard for the validity of claims and defenses is at the core of the definition of an "exceptional" case under § 285. *See Mathis*, 857 F.2d at 753-54.

Having determined that this case is "exceptional" for purposes of § 285, the Court must next determine whether to exercise its discretion in awarding attorneys' fees. The Court finds that attorneys' fees should be awarded in this case. Under the facts present here, it would be grossly unjust if ONY and Forest were left to bear the burden of their own counsel fees. Abbott acted in bad faith and injured ONY and Forest by subjecting them to an unwarranted infringement claim and an unwarranted appeal, thereby forcing them to defend at great expense their right to compete freely. The provision for attorneys' fees under § 285 is available as a deterrent to such conduct.

Abbott contends that attorneys' fees are not appropriate in this case because ONY and Forest have already received a

remedy for Abbott's bad faith conduct, *i.e.*, a judgment of estoppel prohibiting Abbott from enforcing its patents. Such an argument, however, ignores § 285 and the purpose behind it. Section 285 is intended to be a deterrent to unwarranted infringement claims and to prevent injustice to those falsely accused of infringing. Although it is true that the Court's judgment of equitable estoppel allowed Forest and ONY to sell Infasurf® without interference from Abbott, that judgment did not make Forest and ONY whole. They were forced to a substantial amount of money in counsel fees before they could obtain that judgment. Failure to award attorneys' fees under such circumstances could encourage other patentees who are guilty of bad faith conduct similar to Abbott's to bring unwarranted infringement claims in the hope of forcing the alleged infringer to settle the claims rather than expend substantial financial resources litigating them.

Abbott also argues that the Court should decline to award attorneys' fees because this was a close case for equitable estoppel, as evidenced by the advisory jury verdict finding no estoppel. The Court finds this argument unpersuasive. The Court rejected the jury's advisory verdict because in the Court's view, it was not consistent with the evidence presented at trial. The Court has made specific findings of fact in its Equitable Estoppel Decision regarding Abbott's bad faith conduct. These facts show by clear and convincing evidence that Abbott was acting in bad faith before the litigation and continued acting in bad faith by pursuing its infringement claim in the fact of such facts. Simply because the jury failed to come to the same conclusion as the Court does not necessarily make this a close case.

Finally, Abbott argues that attorneys' fees should not be awarded because it was ONY and Forest, not Abbott, who brought the lawsuit. This situation was addressed by the Federal Circuit in *Machinery Corp. of Am.*, 774 F.2d at 474. There, the Circuit Court considered the situation where a declaratory judgment action is brought against a patentee by an erroneously accused infringer and concluded that the trial court could consider whether the patentee acted in bad faith in making the threats of infringement that led to the filing of the declaratory judgment action and whether the alleged infringer reasonably believed its only or best recourse was to file suit. *Id.*

Here, as already stated, the Court finds that Abbott was acting in bad faith by making its threats of infringement. Forest and ONY acted reasonably when confronted with these threats. Accordingly, the fact that it was ONY and Forest that brought the lawsuit rather than Abbott is of no consequence.

In sum, the Court finds that Abbott's bad faith conduct makes this an "exceptional" case for purposes of § 285, and that Abbott should be required to pay attorneys' fees in order to prevent a gross injustice to ONY and Forest and to deter Abbott and other patentees from similar conduct in the future.

2. *Tokyo Tanabe*

The Court finds that ONY and Forest have failed to establish that this is an "exceptional" case for purposes of § 285 with regard to Tokyo Tanabe. As the Court found in its Equitable Estoppel Decision, ONY and Forest failed to show

at trial any misleading or bad faith conduct on the part of Tokyo Tanabe. Although Tokyo Tanabe was aware of Forest's and ONY's activities, there was no relationship between Tokyo Tanabe and ONY which created a clear duty to speak, as there was between Abbott and ONY. Tokyo Tanabe simply stated in the background and remained silent. Such conduct, without more, does not make this an "exceptional" case under § 285.

Forest and ONY also argue that this is an "exceptional" case for purposes of § 285 because, as both this Court and the Federal Circuit found, Abbott and Tokyo Tanabe failed to present any evidence regarding the water content of CLSE, and therefore could not have possibly succeeded on their infringement claim. Though this is a close call, the Court finds that an award of attorneys' fees based on Abbott's and Tokyo Tanabe's failure to prove their infringement claim is not warranted in this case. Although Abbott and Tokyo Tanabe failed to present any direct evidence to prove the water content of CLSE, they did present plausible yet untenable arguments regarding claim construction and the doctrine of equivalents. "Mere error [in concluding that a patent was infringed] does not approach the level of bad faith or gross negligence necessary to characterize a case as exceptional." *Machinery Corp. of Am.*, 774 F.2d at 474.

In sum, the Court finds that an award of attorneys' fees against Tokyo Tanabe is not warranted under the facts and circumstances present here.

Appendix C

CONCLUSION

For the reasons stated, the Court grants plaintiffs' motion for attorneys' fees and expenses with regard to defendant Abbott, but denies the motion with regard to defendant Tokyo Tanabe. In order to assist the Court in determining the proper amount of attorneys' fees and costs to which plaintiffs are entitled, it is hereby

ORDERED that, pursuant to Rules 53 and 54(d)(2)(D) of the Federal Rules of Civil Procedure, Michael R. McGee, Esq., of the law firm of McGee & Gelman, 200 Summer Street, Buffalo, New York 14222, is appointed as a Special Master for the purpose of hearing evidence and reporting on the reasonable amount of attorneys' fees and expenses that Abbott should pay plaintiffs; defendants' objections to the plaintiffs' Bill of Costs; the amount of pre-judgment and/or post-judgment interest, if any, to which plaintiffs are entitled; and other related matters; and

IT IS FURTHER ORDERED that the Special Master shall have all the rights, powers and duties set forth in this Order and in Rules 53 and 54 of the Federal Rules of Civil Procedure; and

IT IS FURTHER ORDERED that the Special Master may communicate with the Court *ex parte*, either orally or in writing, and may divulge to the Court, in such communications, confidential information related to him by the parties, which confidences shall be preserved by the Court; and

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IT IS FURTHER ORDERED that the Special Master shall submit his report, pursuant to Rule 53(e), including recommended findings of fact and conclusions of law, by no later than April 1, 2002, whereupon this reference shall terminate, unless extended by further order of the Court; and

IT IS FURTHER ORDERED that the Special Master shall be compensated for his services at a rate of $325 per hour for time spent at any hearing, meeting or conferences with counsel and at a rate of $225 per hour for all other time, together with all reasonable and necessary expenses incurred by him in the performance of his duties, and may employ an associate attorney of his firm, whose services shall be charged at the rate of $165 per hour; and

IT IS FURTHER ORDERED that within thirty (30) days following the termination of this reference, the Special Master shall provide the Court and the parties with a statement itemizing his hours worked and expenses incurred in connection with this reference; and

IT IS FURTHER ORDERED that the Special Master's fee and expenses shall be assessed or apportioned amongst the parties as justice may require at the termination of the reference, except that the Special Master may apply for interim compensation if the reference is extended; and

IT IS FURTHER ORDERED that the parties shall forthwith submit to the Special Master a copy of all previous submissions regarding attorneys' fees and costs; and

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IT IS FURTHER ORDERED that the Clerk of the Court shall furnish the Special Master with a copy of this Order; shall make the file in this matter available to the Special Master for his review upon request; and shall provide copies of materials therein as needed, without cost.

IT IS SO ORDERED

s/ Richard J. Arcara
RICHARD J. ARCARA
UNITED STATES DISTRICT COURT

Dated: September 4, 2001

APPENDIX D — OPINION OF THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF NEW YORK DECIDED JUNE 23, 1999

UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF NEW YORK.

CASE NUMBER: 96-CV-159-A

FOREST LABORATORIES, INC. AND ONY, INC.,

Plaintiffs,

v.

ABBOTT LABORATORIES AND
TOKYO TANABE COMPANY, LTD.,

Defendants.

INTRODUCTION

Currently before the Court is plaintiffs' motion following trial for entry of a judgment that defendants are equitably estopped from asserting infringement of the patents in suit.[1] Oral argument on the motion was held on January 15, 1999. After carefully considering the evidence adduced at trial, reviewing the submissions of the parties, and hearing argument from counsel, the Court finds that defendants are

1. Also pending are the parties' post-trial motions, pursuant to Federal Rules of Civil Procedure 50(b) and 59, on the issues of claim construction, infringement, validity, and willful infringement. The Court will address those motions in a separate Decision and Order.

equitably estopped from asserting infringement of the patents in suit. The following discussion constitutes the Court's findings of fact and conclusions of law pursuant to Federal Rule of Civil Procedure 52(a).

DISCUSSION

I. General Background

The following is a summary of the Court's findings of fact regarding the general background of this case.

A. Patents in Suit

This case involves two patents owned by defendant Tokyo Tanabe Company, Ltd. ("Tokyo Tanabe"). U.S. Patent No. 4,338,301 (the " '301 patent"), entitled "Lung Tissue Extract Useful For Treating Hyaline-Membrane Disease And Method For Producing The Extract," was issued on July 6, 1982 to Tokyo Tanabe as assignee. U.S. Patent No. 4,397,839 (the " '839 patent"), entitled "Surface Active Material And Process For Preparing Same," was issued on August 9, 1983 to Tokyo Tanabe as assignee. Both patents relate to pharmaceutical compositions used to treat Respiratory Distress Syndrome in premature babies. The '301 patent expires on May 21, 2000, and the '839 patent expires on June 1, 2005.[2]

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2. The '301 and '839 patents are referred to collectively herein as the "Tokyo Tanabe patents."

Appendix D

B. RDS and Lung Surfactant

Respiratory Distress Syndrome ("RDS") is, when untreated, an often fatal condition that afflicts thousands of premature infants throughout the world each year. Until relatively recently, RDS was the leading cause of mortality in premature infants.

The search for a cure for RDS was the subject of research by scientists throughout the world for almost 35 years. In 1959, Dr. Mary Ellen Avery discovered that premature infants suffering from RDS had an insufficient amount of a substance known as "pulmonary surfactant" in their lungs. Dr. Avery theorized that surfactant might be produced by specialized cells in the lung and that the lungs of premature babies might not be developed enough to produce a sufficient amount of surfactant. Subsequent research has shown that Dr. Avery's theory was correct.

Today, it is accepted that lung surfactant is essential to respiration. During the process of breathing, air is inhaled into the lung and passes through a tree-like network of bronchial tubes which branch and divide again into smaller and smaller passages. The most diminutive "twigs" in the bronchial passages are bronchioles which are under one millimeter in diameter. The bronchioles end in tiny air ducts which lead to groupings of microscopic air sacs called alveoli, each of which is a mere one thousandth of an inch across. A developed lung contains hundreds of millions of alveoli which are arrayed on bronchial passages like tiny clusters of grapes.

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It is through the alveoli that oxygen and carbon dioxide are exchanged in the bloodstream. Each alveolus is lined with a watery fluid that enables oxygen and carbon dioxide to diffuse through the single-cell alveolar walls. The gasses then pass through the alveoli into an entwining network of extremely small blood vessels called capillaries. During respiration, the alveoli expand and contract as fresh air is inhaled and oxygen-depleted air is exhaled.

In the absence of surfactant, the high surface tension of the watery coating in the interior of the alveolus tends to pull the alveolar walls inward until the alveolus collapses. In normally developed lungs, the stability of the alveoli is regulated by the presence of lung surfactant. Surfactant possesses "surface active properties," which simply means that it reduces surface tension. These properties are inversely related to surface area. Thus, surfactant has proportionately greater surface tension-reducing effects on smaller areas and diminished effects on larger areas. These characteristics make respiration possible. The reduction of surface tension created by the presence of lung surfactant keeps the alveoli relatively rigid and prevents them from collapsing as they are deflated.[3] Conversely, the diminished effect of surfactant in larger areas results in relatively higher surface tension in the expanded alveolus causing it to recoil rapidly during exhalation.

The lungs of babies with RDS have not developed to the point that they produce surfactant naturally. As a result, the high surface tension in the alveoli requires a tremendous

3. Surfactant molecules disperse themselves between fluid molecules, reducing the cohesive force between them. The term surfactant is derived from the phrase "surface active."

amount of energy to inflate them. During exhalation, the increased surface tension of the contracted alveoli tends to cause the alveoli to collapse entirely, making it exceedingly difficult for them to reopen and causing extremely labored breathing and inefficient respiration. As a result, the skin of babies with RDS often has a bluish cast because of the lack of oxygen in the blood and tissues. Left untreated, a premature baby suffering from RDS will usually not survive.

C. Development of a Treatment for RDS

In the decades that followed Dr. Avery's research, researchers throughout the world worked on developing a treatment for RDS. Early treatments for RDS included: (1) forcing air or oxygen into the airway of the patient through a tube; (2) using steroid treatments; and (3) forcing supplements of certain components believed to be present in the pulmonary surfactant into the patients. Unfortunately, these treatments did not significantly reduce RDS mortality rates. The use of respirators, in fact, tended to damage the structure of the fragile lungs of the premature infants.

During the 1960's, 1970's and 1980's, different groups of researchers investigated what has come to be known as "surfactant replacement therapy." Surfactant replacement therapy involves replacing the surfactant missing from a premature baby's lungs with surfactant from some other source.

Different groups of researchers studied the possibility of using surfactant from animals, such as cows and sheep, as a possible source of replacement surfactant. However, it was thought that the presence of a significant amount of animal protein in such surfactant might be harmful to humans. One

team of researchers headed by Dr. John Clements tried to solve this dilemma by developing an entirely synthetic surfactant, but the compound proved ineffective.

D. Dr. Fujiwara and the Tokyo Tanabe Patents

During the 1960's and 1970's, Dr. Tetsuro Fujiwara, a Japanese pediatrician and biochemist, worked together with Dr. Forrest Adams at the University of California at Los Angeles Medical School to study surfactant in large animals. Their research built on studies done by Dr. Goran Enhorning of the University of Western Ontario, Canada, on surfactant in smaller animals. When funding for Dr. Fujiwara's research in the United States ended, he returned to Japan and continued his research there.

After his return to Japan, Dr. Fujiwara began working with researchers at defendant Tokyo Tanabe, a pharmaceutical company in Tokyo, Japan. With the assistance of Dr. Yuji Tanaka and Dr. Tsunetomo Takei of Tokyo Tanabe, Dr. Fujiwara researched cow-lung surfactant and eventually developed a surfactant replacement composition derived from cows' lungs. More specifically, under the method invented by Dr. Fujiwara, the lungs of freshly-slaughtered cows are removed and then minced. The minced cow-lung material is then processed and the surfactant is extracted.

In October 1978, at a hospital in Japan, Dr. Fujiwara attempted for the first time to use his newly-developed surfactant composition to treat a premature human baby with RDS. The treatment was effective and the baby survived.

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Dr. Fujiwara and the Tokyo Tanabe researchers immediately conducted additional testing of the composition and its effectiveness in treating RDS. On June 2, 1979, Dr. Fujiwara and Tokyo Tanabe filed a patent application for their new surfactant composition in Japan. On May 21, 1980, a patent application was filed in the United States naming Drs. Fujiwara, Tanaka and Takei as inventors. As stated above, the United States Patent and Trademark Office ("PTO") issued the '301 patent on July 6, 1982.

After additional research, Dr. Tanaka of Tokyo Tanabe discovered that adding certain lipids known as free fatty acids enhanced the surface activity of the '301 composition thereby making it more effective. Dr. Tanaka filed for a patent on his discovery in Japan on September 10, 1981 and subsequently filed for a patent in the United States. As stated above, the PTO issued the '839 patent on August 9, 1983.

E. Dr. Egan, Dr. Notter, CLL, CLSE and Infasurf

Dr. Edmund A. Egan is a pediatric physician, a faculty member at the State University of New York at Buffalo ("U.B.") Medical School, and president of plaintiff ONY, Inc. ("ONY"). Dr. Egan is certified in neonatology, which is the branch of pediatrics dealing with newborn infants, and was formerly head of the Newborn Medical Program at Children's Hospital in Buffalo, New York and chief of the Neonatology Division in the Department of Pediatrics at the U.B. Medical School.

Dr. Egan first began researching the functions and diseases of the lung in about 1973. In the spring of 1980, he

began collaborating with Drs. Donald Shapiro and Robert Notter, who were both associated with the University of Rochester Medical School and Strong Memorial Hospital in Rochester, New York, for the purpose of developing a surfactant replacement composition for treating premature babies with RDS. Prior to this time, Dr. Egan had been researching lung function and lung disease in premature lambs and Dr. Notter had been researching lung surfactant generally. Dr. Shapiro was chief of neonatology at Strong Memorial Hospital in Rochester and was Dr. Notter's supervisor.

Dr. Notter's research responsibility was to formulate, manufacture, and conduct biophysical testing of the surfactants. Dr. Egan's responsibility was then to evaluate the surfactants biologically in premature lambs. Dr. Shapiro acted as a consultant. The research by Drs. Egan and Notter followed on the research done by Drs. Enhorning, Adams, and Fujiwara.

In January 1981, Dr. Notter developed a surfactant replacement composition derived from surfactant extracted from the lungs of newborn calves. He called the composition Calf Lung Lipids or "CLL." The surfactant extract was obtained by lavaging, or washing it out of, the alveolar spaces of the lungs of freshly slaughtered newborn calves. The name of the extract was eventually changed from CLL to "CLSE," which stands for Calf Lung Surfactant Extract.

In late January or early February 1981, Dr. Notter provided Dr. Egan with CLSE for testing in premature lambs with RDS. In March 1981, Dr. Egan administered the CLSE

to premature lambs and it proved dramatically effective in allowing the lambs to breath normally. Drs. Egan and Notter subsequently published several articles regarding their experiments and laid the groundwork for testing in human babies.

In June 1983, at Children's Hospital in Buffalo, Dr. Egan first used CLSE to treat a premature human baby with RDS. The treatment was successful and marked the first time a human baby was successfully treated with a bovine-derived surfactant in the United States. Dr. Egan thereafter published the results of his work and commenced extensive clinical trials of CLSE over the next several years. Dr. Egan ultimately named the pharmaceutical composition made from CLSE "Infasurf."

F. Commercial Development of Tokyo Tanabe Patents

In early 1983, defendant Abbott Laboratories ("Abbott"), a large pharmaceutical manufacturer headquartered near Chicago, Illinois, began investigating the possibility of commercial development of a lung surfactant composition for treating RDS in premature babies. Abbott already had a large presence in neonatal pharmaceuticals, manufacturing nutritional and other drug products for newborns. Abbott assigned Dr. Alan J. Gold, its Medical Director of Pharmaceuticals, to conduct the investigation.

As part of his investigation, Dr. Gold considered whether Abbott should enter into a licensing agreement with Tokyo Tanabe to develop a surfactant based on the '301 and '839

patents. In August 1983, Dr. Gold spent two days in Japan meeting with Dr. Fujiwara and representatives of Tokyo Tanabe regarding their work on pulmonary surfactants.

During his investigation, Dr. Gold also became aware of CLSE and the work of Drs. Egan and Notter and arranged a meeting with them. In November 1983, Dr. Gold met with Drs. Egan, Notter, and Shapiro in Rochester and learned from them "virtually everything" about CLSE, including the development, composition and testing of the surfactant. Trial Transcript ("Tr.") at 4938. At that meeting, Dr. Gold told the three doctors that Abbott wanted to produce a product that would be protected by a patent. Drs. Egan, Notter and Shapiro hoped that Abbott would take over the commercial development of CLSE. Eventually, however, Abbott decided to proceed with the Tokyo Tanabe product instead because, unlike CLSE, it was covered by patents. Abbott subsequently informed Drs. Egan, Notter and Shapiro of its decision.

On February 3, 1984, Tokyo Tanabe granted Abbott an exclusive license for the Tokyo Tanabe patents in the United States. Plaintiffs' Trial Exhibit ("PTX") 20. After being granted the license, Abbott developed a commercial product, based on the Tokyo Tanabe patents, called "Survanta." Abbott first used Survanta in clinical trials in the United States in 1985, more than two years after the first baby in this country was treated with CLSE. Abbott eventually sought approval from the United States Food and Drug Administration ("FDA") to market Survanta. On July 1, 1991, the FDA approved Survanta for the treatment of RDS in premature babies. At the same time, the FDA granted Abbott a seven-

year period of market exclusivity under the Orphan Drug Act, 21 U.S.C. §§ 360aa-360dd.[4]

G. Formation of ONY, ONY's Agreement With Forest, and Abbott's Claim of Infringement

In 1985, Dr. Egan formed ONY,[5] a small pharmaceutical company, for the sole purpose of developing CLSE and making it available to children. ONY has a manufacturing plant in Amherst, New York and employs approximately 20 employees. ONY manufactures only Infasurf and has no plans to manufacture any other type of drug. Dr. Egan gave up his full-time job at Children's Hospital and his full-time position at the U.B. Medical School in order to run ONY.

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4. The Orphan Drug Act creates a financial incentive for the development of drugs for rare diseases or conditions. A "rare disease or condition" is one which affects less than 200,000 persons in the United States or which affects more than 200,000 persons and for which there is no reasonable expectation that the cost of developing and marketing the drug will be recovered from sales in the United States. 21 U.S.C. § 360bb(a)(2).

The most important financial incentive under the Act is a seven-year period of market exclusivity granted to the first designated drug that is approved by the FDA for a particular disease or condition. 21 U.S.C. § 360cc(a). The FDA enforces this market exclusivity by denying all subsequent applications for the "same drug" used for the same therapeutic purpose. 21 C.F.R. § 316.3(b)(12).

5. ONY stands for Ontario/ New York. Dr. Egan chose this name because the scientists who were helping to organize ONY were from Ontario, Canada and New York State.

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In June 1985, the FDA granted ONY's request for preliminary designation of Infasurf as an Orphan Drug. By March 1986, ONY had received Investigational New Drug ("IND") status from the FDA and was granted what is commonly referred to as a "treatment IND," which allowed ONY to conduct clinical trials using Infasurf.

In June 1991, ONY entered into an agreement with plaintiff Forest Laboratories, Inc. ("Forest") to develop and market Infasurf. Forest is a pharmaceutical company located in New York City. In the agreement, ONY warranted to Forest that ONY was the sole and exclusive owner of the rights to Infasurf and agreed to indemnify Forest for the cost of settling any claims brought by any third parties.

In June 1994, Carl A. Spalding, Vice President and General Manager of Abbott's Pediatric Products Division, wrote a letter to Forest's President, Howard Solomon, stating that, in Abbott's opinion, there was reason to believe that Infasurf might infringe the Tokyo Tanabe patents. Prior to this letter, neither Abbott nor Tokyo Tanabe had ever mentioned to Dr. Egan, ONY, or Forest that Infasurf might infringe the Tokyo Tanabe patents.

On March 13, 1995, ONY submitted a new drug application ("NDA") to the FDA for approval to market Infasurf. On May 24, 1996, the FDA notified ONY that Infasurf and Survanta are the "same drug" for purposes of the Orphan Drug Act. *See* 21 C.F.R. § 316.3(b)(13). Accordingly, under the Act, the FDA would not approve the sale of Infasurf until July 1, 1998, the date on which Abbott's seven-year period of market exclusivity was to expire.

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H. Instant Lawsuit

On March 8, 1996, ONY and Forest commenced the instant action seeking a declaratory judgment that Infasurf does not infringe the Tokyo Tanabe patents. They also seek a declaratory judgment that the Tokyo Tanabe patents are invalid or that, in the alternative, Tokyo Tanabe and Abbott should be estopped from enforcing the patents under the doctrine of equitable estoppel.

Tokyo Tanabe and Abbott counterclaimed that Infasurf infringes the Tokyo Tanabe patents. They claim that such infringement is willful. They seek a permanent injunction that would prevent ONY and Forest from manufacturing and marketing Infasurf until after both patents expire.

A jury trial commenced on June 12, 1998. Prior to trial, defendants moved to strike plaintiffs' equitable estoppel defense. By Decision and Order filed June 12, 1998, the Court denied defendants' motion and ruled, pursuant to Federal Rule of Civil Procedure 39(c), that it would use the jury in the case as an advisory jury on the issue of equitable estoppel. On August 10, 1998, the Court issued a Decision and Order explaining its reasoning for the June 12, 1998 Decision and Order.

On July 1, 1998, during the trial, the FDA approved the sale of Infasurf, but plaintiffs agreed to maintain the status quo until the end of the trial. On September 11, 1998, the jury returned a verdict in favor of the defendants, Abbott and Tokyo Tanabe, on the issues of infringement and validity. The jury also rendered an advisory verdict in favor of

defendants on the issue of equitable estoppel. The jury also determined, however, that plaintiffs' infringement was not willful.

II. Jury's Advisory Verdict on Equitable Estoppel is not Binding

Equitable estoppel is an equitable defense to a claim of patent infringement and, as such, must ultimately be decided by the Court, not a jury. *ABB Robotics, Inc. v. GMFanuc Robotics, Inc.*, 52 F.3d 1062, 1063 (Fed. Cir. 1995) ("estoppel is an equitable defense to a charge of patent infringement . . . Being an equitable doctrine, estoppel is committed to the sound discretion of the trial judge"), *cert. denied,* 516 U.S. 917 (1995); *cf. Paragon Podiatry Lab. v. KLM Labs.*, 984 F.2d 1182, 1190 (Fed. Cir. 1993) ("defense of inequitable conduct in a patent suit, being entirely equitable in nature, is not an issue for the jury to decide"). In this case, the Court used an advisory jury on the issue of equitable estoppel. The jury found that equitable estoppel does not apply.

Federal Rule of Civil Procedure 52(a) provides that "in all actions tried upon the facts without a jury or with an advisory jury, the court shall find the facts specially and state separately its conclusions of law thereon." The use of an advisory jury does not replace the Court as the true trier of fact. The responsibility for rendering a decision always remains with the Court. The verdict of an advisory jury has no binding effect; the Court may accept the advisory verdict in whole or in part, or disregard it completely. *See Ragin v. Harry Macklowe Real Estate Co.*, 6 F.3d 898, 907 (2d Cir. 1993).

Here, the Court rejects the jury's advisory verdict on equitable estoppel because it finds that the proof at trial established by a preponderance of the evidence that Abbott and Tokyo Tanabe should be estopped from asserting a claim of patent infringement against ONY and Forest.

III. Legal Standards for Equitable Estoppel

Equitable estoppel is not limited to a particular factual situation, or subject to simple, hard and fast rules. Nevertheless, the Federal Circuit has articulated a three-part test to guide courts in determining whether the doctrine of equitable estoppel should to be applied to bar recovery. *See Gasser Chair Co. v. Infanti Chair Mfg. Co.*, 60 F.3d 770, 775 (Fed. Cir. 1995); *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1041 (Fed. Cir. 1992). First, the alleged infringer must show that the patentee, through misleading conduct, led the alleged infringer to reasonably infer that the patentee did not intend to enforce its patent against the infringer. Second, the alleged infringer must demonstrate reliance on that conduct. Finally, the alleged infringer must show that it will be materially prejudiced if the patentee is permitted to proceed with an enforcement claim against the alleged infringer. *A.C. Aukerman*, 960 F.2d at 1028, 1041. In order to prevail, the alleged infringer must establish each of these elements by a preponderance of the evidence. *Id.* at 1045-46. Once established, this defense bars all relief on the patentee's claims of infringement. *Id.* at 1028, 1041.

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A. Misleading Conduct

The first element of equitable estoppel that the alleged infringer must show is that the patentee, through misleading conduct, led the alleged infringer to reasonably infer that the patentee did not intend to enforce its patent against the infringer. In order to prove misleading conduct, the alleged infringer must show that the patentee somehow communicated to the alleged infringer that it did not intend to press an infringement claim. *Id.* at 1042. The alleged infringer may satisfy this requirement by producing evidence of affirmative statements or conduct by the patentee from which it is reasonable to infer that the patentee was not going to pursue an infringement claim. *Id.*

Misleading conduct by the patentee may also take the form of silence, if the patentee had a clear duty to speak or such silence was accompanied by some other factor indicating that the silence was sufficiently misleading to amount to bad faith. *ABB Robotics*, 52 F.3d at 1064; *A. C. Aukerman*, 960 F.2d at 1042-44. For example, in the most common scenario, the patentee expressly objects to the alleged infringer's activities, but does not follow up with an infringement lawsuit for some period of years. This is not the only way, however, that silence can be misleading conduct for equitable estoppel purposes. *ABB Robotics*, 52 F.3d at 1064. Rather, inaction "combined with other facts respecting the relationship or contacts between the parties" may "give rise to the necessary inference that the claim against the [alleged infringer] is abandoned." *Id.* (quoting *A. C. Aukerman*, 960 F.2d at 1042); *see also Scholle Corp. v. Blackhawk Molding Co.*, 133 F.3d 1469, 1472 (Fed. Cir. 1998) ("When the course of dealings

between a patentee and an alleged infringer is such that the alleged infringer reasonably infers from the patentee's misleading conduct or inaction that the patentee has waived its patent rights, then the first element of equitable estoppel has been established absent a statement to the contrary by the patentee."); *R2 Med. Sys. v. Katecho, Inc.*, 931 F. Supp. 1397, 1417 (N.D. Ill. 1996) ("For instance, such a duty [to speak] may arise . . . where the patentee's conduct encourages the subsequently challenged activity."); *Stambler v. Diebold, Inc.*, 11 U.S.P.Q.2d 1709, 1715 (E.D.N.Y. 1988) (finding that patent owner had a duty to speak and its silence was intentionally misleading where it had long known of the alleged infringement and permitted the conduct to continue), *aff'd without op.*, 878 F.2d 1445 (Fed. Cir. 1989).

In order to satisfy the misleading conduct requirement, the alleged infringer need not prove that the patentee's misleading of the alleged infringer was intentional. *A. C. Aukerman*, 960 F.2d at 1043. The question is whether the alleged infringer was, in fact, misled. Of course, if there is evidence of an intent to mislead, that weighs in favor of applying equitable estoppel. *Id.*

B. Reliance

The second element of equitable estoppel that an alleged infringer must show is reliance. In order to prove reliance, the alleged infringer must show that it "had a relationship or communication with the [patentee] which lulled the infringer into a sense of security" that the infringer's conduct would not invite an infringement suit. *Id.*; *see also ABB Robotics*, 52 F.3d at 1064. The fact that an alleged infringer failed to

take affirmative actions to protect itself from an infringement lawsuit is evidence of its reliance. *See ABB Robotics, Inc. v. GMFanuc Robotics Corp.*, 828 F. Supp. 1386, 1398-1400 (E.D. Wis. 1993), *aff'd*, 52 F.3d 1062 (Fed. Cir. 1995); *Wafer Shave, Inc. v. Gillette Co.*, 857 F. Supp. 112, 124 (D. Mass. 1993), *aff'd without op.*, 26 F.3d 140 (Fed. Cir. 1994).

C. Prejudice

The third element of equitable estoppel that the alleged infringer must show is that it will be materially prejudiced if the patentee is permitted to proceed with an enforcement claim against the alleged infringer. Prejudice may be either economic or evidentiary. *A.C. Aukerman*, 960 F.2d at 1033, 1043. Economic prejudice may be a change of economic position during the period of delay. *Id.* For example, economic prejudice may arise where the alleged infringer will suffer the loss of monetary investments or incur damages which likely would have been prevented had the patentee asserted its infringement claim earlier. *Id.* at 1033.

Evidentiary prejudice occurs where an alleged infringer is unable "to present a full and fair defense on the merits, due to the loss of records, the death of a witness, or the unreliability of memories of long past events." *Id.*; *Advanced Hydraulics, Inc. v. Otis Elevator Co.*, 525 F.2d 477, 482 (7th Cir.) (finding prejudice where crucial witness died), *cert. denied*, 423 U.S. 869 (1975); *Wafer Shave*, 857 F. Supp. at 126 (holding that lost opportunity to preserve important documentary and testimonial evidence constitutes prejudice); *Motorola, Inc. v. CBS, Inc.*, 672 F. Supp. 1033, 1037

(N.D. Ill. 1986) (holding that a long time lag leads inevitably to some loss of memory and documentation).

IV. Findings of Fact Regarding Equitable Estoppel

Applying the above legal principles to the instant case, the Court finds by a preponderance of the evidence that Abbott misled ONY and Forest into believing that Abbott would not assert an infringement claim against them, that ONY and Forest reasonably relied on Abbott's misleading conduct, and that ONY and Forest will be materially prejudiced if Abbott is now permitted to proceed with an infringement claim against them. The following facts are those the Court finds have been established that support this conclusion.

A. Misleading Conduct

ONY and Forest have shown by a preponderance of the evidence that Abbott, through misleading conduct, led them to reasonably infer that Abbott did not intend to enforce the Tokyo Tanabe patents against them. This is not, as defendants contend, a case involving mere silence or inaction on the part of the patentee. To the contrary, the evidence shows that between 1983 and 1994, Abbott was fully aware of ONY's and Forest's activities and, in fact, up until 1991, Abbott actively encouraged Dr. Egan and ONY in their efforts to develop CLSE. Such conduct created a duty on the part of Abbott to advise ONY and Forest about possible infringement of the Tokyo Tanabe patents. Yet, Abbott never mentioned infringement until June of 1994, eleven years after it first learned about CLSE.

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The evidence also shows that the reason Abbott kept encouraging Dr. Egan in his efforts to develop CLSE, even though he was developing a potentially competing product, was because Abbott wanted to keep its options open in case Survanta did not succeed for some reason. After Survanta finally obtained FDA approval, Abbott stopped stringing along Dr. Egan and asserted its infringement claim against ONY and Forest.

1. Abbott's Contacts with Drs. Egan and Notter

a. Initial Encouragement and Patentability Search

Even after Abbott decided in February 1984 to proceed with development of the Tokyo Tanabe product rather than CLSE, Abbott encouraged Drs. Egan, Notter and Shapiro to continue their work and solicited from them more information about CLSE. In March 1984, Dr. Gold sent a confidential disclosure form to Dr. Shapiro seeking information about CLSE for the purpose of evaluating its patentability. Defendants' Trial Exhibit 473. The last sentence of Dr. Gold's letter states, "once again, I appreciate your willingness to work with us and I look forward to developing a productive relationship." The attached confidentiality agreement says "this letter will confirm the interest of Ross Laboratories Division of Abbott Laboratories ('Ross') in receiving certain information from you. . . ." At this time, Abbott had not yet started clinical trials with the Tokyo Tanabe product and was pessimistic about receiving a treatment IND from the FDA to allow such testing. *See* PTX 317.

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In April 1984, pursuant to Abbott's request, Drs. Egan, Notter, and Shapiro submitted a Memorandum of Invention ("MOI") to Abbott. The MOI disclosed the details of everything known about CLSE, including its use and its method of manufacture. *See* PTX 665. The MOI explained that aqueous suspensions of CLSE had first been used successfully with lambs in March 1981 and that at the time of the MOI, CLSE was being used in ongoing clinical trials in human babies. Upon receipt of the MOI, Dr. Gold arranged for Abbott's patent department to do a patentability search.

Dr. Gold had previously told Drs. Egan and Notter that Abbott was concerned about patentability and was only interested in a product that had patent protection. He also told them that Abbott had elected to commercialize the Tokyo Tanabe product instead of CLSE because the Tokyo Tanabe product had patent protection and CLSE did not. Thus, Drs. Egan and Notter submitted the MOI to Abbott in the hope that there would be something patentable about CLSE and, as a result, Abbott would develop it.

Dr. Egan explained that he and Drs. Notter and Shapiro "were hoping that we would convince Abbott to commercialize CLL and make it available to children." Tr. 6003-04. He also testified that he understood that, as far as Abbott was concerned, patent protection "would seem to be the deciding and crucial difference, as far as the corporate people were concerned. So we were trying to see if we could get something, some patent protection for our material." Tr. 6004.

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On May 29, 1984, Abbott's patent counsel, Margaret M. O'Brien, responded by letter to the MOI (the "O'Brien letter"). Ms. O'Brien concluded that "the chances of obtaining significant patent protection" for the CLSE product itself or the process for making CLSE was minimal. PTX 41. Ms. O'Brien also enclosed "the pertinent references" she found. Those references were a 1982 article by Dr. Notter and an April 1981 abstract by John A. Smyth and others. PTX 41. Despite the fact that in February 1984, Abbott had become the exclusive licensee of the Tokyo Tanabe patents and therefore had a vested interest in ensuring that those patents were not infringed, Ms. O'Brien did not mention the Tokyo Tanabe patents in her letter and did not attach them as "pertinent references." She gave no indication whatsoever of possible infringement of the Tokyo Tanabe patents. Even though she purported to have completed a patentability search for the "surfactant extract," that is, CLSE, she did not indicate in any way that CLSE was not patentable due to the existence of the Tokyo Tanabe patents.

Ms. O'Brien did, however, compliment the work of Drs. Egan and Notter as "outstanding" and concluded: "we look forward to working with you in the future." PTX 41. In short, she encouraged Drs. Egan and Notter to continue their work on CLSE even though in February 1984, Abbott had just obtained an exclusive license to the Tokyo Tanabe patents.[6]

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6. Ms. O'Brien's letter stated in its entirety:

> We have completed a patentability search for your surfactant extract and process for making the extract.
>
> (Cont'd)

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Dr. Egan testified that when his group received the O'Brien letter, "we were very disappointed. We really wanted Abbott to commercialize our material." Tr. 6007. He also explained his understanding that:

> there was no real patentability of our product. And we also concluded that our product was not covered under whatever patents covered the surfactant that Abbott had licensed from Tokyo Tanabe. Because if our material had been covered by those patents, that would have solved our problem. Then there would have been patent protection for our material, and that would have been great with us.

Tr. 4976.

Dr. Egan also testified that as a result of the O'Brien letter:

> I was given to understand that neither the process nor the material was patentable. And that it was

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(Cont'd)

> We are enclosing copies of the pertinent references found in our search.
>
> Based on these references, we believe that the chances of obtaining significant patent protection for the extract and process are minimal.
>
> We wish to thank you for your disclosure and the opportunity to evaluate your outstanding work in the preparation of a surfactant extract. We look forward to working with you in the future. Please do not hesitate to call us if you have any questions or comments.

> in the public domain. And that I think by inference, that it wasn't clearly covered by the patents that covered whatever surfactant they had licensed from Japan.

Tr. 6007.

Likewise, Dr. Notter explained that he concluded that if the Tokyo Tanabe patents covered CLSE, Abbott could make CLSE and have patent protection. When Abbott said that CLSE was not patentable and that Abbott would not develop it, Dr. Notter understood that to mean that CLSE was not covered by "any patents, including the Tokyo Tanabe patents." Tr. 3360.

From this evidence, the Court concludes that the O'Brien letter was an important instance of misleading conduct by Abbott. Abbott solicited Dr. Egan and his group to provide detailed information regarding CLSE for the purpose of determining its patentability. Dr. Egan and his group complied with the request by submitting the MOI. The O'Brien letter informed Dr. Egan's group that CLSE was not patentable in light of "the pertinent references" attached to the letter. Unexplainably, the letter made no mention of the Tokyo Tanabe patents nor were they attached as "pertinent" references. Based on this omission, it was certainly reasonable for Dr. Egan and his group to infer that the Tokyo Tanabe patents were not "pertinent" to CLSE. Dr. Egan testified credibly that he was aware of the Tokyo Tanabe patents and inferred from their omission from the letter that CLSE was not covered by them.

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Having voluntarily undertaken to do a patentability search for CLSE, Abbott assumed a clear duty to inform Dr. Egan and his group of any patents, including the Tokyo Tanabe patents, that already covered his product. Obviously, a product is not patentable if it is already covered by an existing patent. Abbott did not mention the Tokyo Tanabe patents in its patentability search for CLSE, yet now claims that CLSE infringes those same patents.

Whether the omission of the Tokyo Tanabe patents from the O'Brien letter was intentional or merely negligent is irrelevant for purposes of the equitable estoppel analysis. What is relevant is that the letter misled Dr. Egan and his group into believing that Abbott would not make a claim of infringement against CLSE based on the Tokyo Tanabe patents.

b. Contacts Between June 1984 and April 1986

After sending the O'Brien letter, Abbott continued to ask for and receive information about CLSE. For example, on numerous occasions, Dr. Notter provided samples of CLSE to Drs. Victor Taylor, Darryl Absolom and Ken Hahn of Abbott for testing. Dr. Taylor also spent time in Dr. Notter's laboratory, learning to use the Wilhelmy surface balance, an instrument used to measure surface tension, and seeing it applied to CLSE.

In 1984, sometime after the O'Brien letter was sent, Dr. Notter actually became a consultant for Abbott and continued as such until 1991. During Dr. Notter's

consultancy, Abbott specifically allowed, and in fact encouraged, Dr. Notter to continue working on CLSE and supplying CLSE to Dr. Egan for use in clinical trials at Children's Hospital in Buffalo. At no time during Dr. Notter's consultancy did Abbott tell Dr. Notter to stop his work with CLSE or indicate to him that CLSE might infringe the Tokyo Tanabe patents.

Abbott also continued to follow and encourage Dr. Egan's clinical development of CLSE. To that end, Abbott invited Dr. Egan to present his work on CLSE at a December 1984 conference sponsored by Abbott. Other speakers at that conference included Dr. Avery and Dr. Fujiwara. In May 1985, at a plenary session of the Pediatric Research Meeting, Dr. Gold even congratulated Dr. Egan on his work involving CLSE.

c. April 1986 Meeting

In April 1986, Dr. Gold and Dr. Henry Sauls, the Vice President of Medical Affairs for Abbott, met with Dr. Egan in his office at Children's Hospital in Buffalo. The meeting was initiated by Abbott. The purpose of the meeting was to discuss CLSE and ONY's status and to see whether joint development of CLSE was still possible. Abbott understood that Dr. Egan was "angry" with Abbott, and Abbott apparently wanted to clarify any misunderstanding. Tr. 6150-51. Neither the Tokyo Tanabe patents nor any possible infringement was mentioned at the meeting.

Following the 1986 meeting, Dr. Sauls sent Dr. Egan a letter stating that Abbott was "anxiously awaiting" the results

of ongoing clinical trials involving CLSE and suggesting that "some future collaboration" between Abbott and ONY on CLSE might be possible. PTX 43. Again, there was no mention of possible infringement of the Tokyo Tanabe patents.

In light of this evidence, the Court concludes that the April 1986 meeting was another important instance of misleading conduct by Abbott. At the time of the meeting, Dr. Egan was aware of the Tokyo Tanabe patents and that Abbott was developing a product under those patents. Yet Abbott approached him and inquired about possible joint development of CLSE. Neither the Tokyo Tanabe patents nor any possible infringement was mentioned at the meeting or the subsequent letter from Dr. Sauls. Based on these facts, it was certainly reasonable for Dr. Egan to believe that Abbott had no intention of asserting an infringement claim against him.

d. Contacts Between 1987 and 1991

In early 1987, Abbott was still concerned about the FDA review of Survanta and was afraid that ONY might "somehow achieve[] approval first" and thus "be able to secure seven years [sic] market exclusivity." PTX 248, 326. Abbott therefore maintained its contact with Dr. Egan.

In the fall of 1987, Dr. Egan was again invited to an Abbott-sponsored conference, this time in Arizona. At that conference, Dr. Bruce Holm, who worked with Dr. Notter and Dr. Enhorning, made a presentation about Infasurf. In December 1988, Dr. Egan was invited to participate in

another Abbott-sponsored conference in Washington. He and Dr. Shapiro both made presentations about Infasurf. This seminar, too, was a public recognition of Dr. Egan's contributions to the field. Other participants at that meeting included Drs. Avery and Fujiwara. In December 1990, Dr. Egan again was invited to and participated in yet another Abbott-sponsored conference. Dr. Egan presented results from a study involving Infasurf. Dr. James Kendig also presented results from a study involving Infasurf at that meeting.

Abbott's relationship with Dr. Egan ended abruptly in 1991, around the time Abbott received final FDA-approval to market Survanta. After that time, Abbott cut off contact with Dr. Egan and ONY. For example, Dr. Egan was not invited to any more Abbott-sponsored conferences after Survanta was approved. Dr. Notter's consultancy with Abbott also terminated in 1991.

2. Abbott Monitored CLSE, ONY and Forest

The evidence at trial shows that Abbott closely monitored and was fully aware of the development of CLSE during the 1980's and into the 1990's. Yet Abbott remained silent and sat on its rights.

The evidence showed that Abbott maintained a file identified as "Infasurf(Egan)" which contained press clippings about Infasurf. PTX 812; *see also* PTX 44, 50. Abbott also routinely monitored the surfactant market and the development of potentially infringing products.

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As early as February 1986, Abbott's internal documents discuss ONY and CLSE. *See, e.g.*, PTX 244A. In May 1986, Dr. Gold wrote to Dr. Fujiwara about ONY, stating "there have been some relatively recent developments which you need to know. Dr. Enhorning and Dr. Ted Egan (University of Buffalo) have formed a company called ONY Inc. and plan to commercialize calf lung surfactant extract (CLSE, previously known as CLL)." PTX 42. Dr. Gold went on to say that "they intend to market CLSE in the United States" and described Dr. Enhorning as "a competitor to Ross, Abbott, and Tokyo Tanabe."

In July 1986, Pat Welch, Abbott's Manager of Drug Regulatory Affairs, circulated a memorandum about ONY to several other Abbott employees. The memorandum enclosed a June 30, 1986 announcement reporting that "ONY intends to market Infasurf itself, unless a major pharmaceutical firm becomes interested in the product and buys ONY . . ." PTX 246.

In January 1987, Dr. Gold prepared a memorandum concerning a telephone call he had received from an Abbott territorial manager reporting clinical trials of CLSE at Primary Children's Hospital in Salt Lake City. PTX 325. Dr. Gold noted that "with all the activity, there may be things we don't know about Dr. Egan's plans, and there may be more of a competitive threat than we had believed." Dr. Gold then went on to say, "by way of this memo, I'm asking those listed to seek out whatever information possible about Dr. Egan's activities."

Also in January 1987, Dr. Gold wrote to Tokyo Tanabe, telling them of ONY's formation and ONY's goal of marketing CLSE: "Dr[.] Egan and Dr[.] Enhorning have formed a corporation, ONY Inc[.] to bring CLSE to market in the United States. If they are successful they would compete with Surfactant TA."[7] PTX 46.

In April 1989, Dr. Gold sent an e-mail to Pat Welch about the Infasurf trials. Dr. Gold expressed unhappiness with the attention that Dr. Egan and ONY were receiving from the media, noting: "Egan is still at it. I got a call from a TM [territory manager] in Fort Worth. Apparently Infasurf is being used at some hospital there and the media picked it up and made a big splash out of it on tv [sic] last nite [sic]." PTX 334.

In June 1989, Dr. Gold sent another e-mail regarding Infasurf. Dr. Gold noted that "[a] member hospital, McCoy-D in Ogden, Utah, had reported to them [by a hospital supplier] that a newspaper article in Salt Lake stated that the University of Utah was evaluating a product named Infasurf from a company named ONY, Inc . . ." Dr. Gold acknowledged that he was concerned because "this was creating a major competitive situation in Ogden . . ." PTX 335.

Abbott continued to follow ONY's efforts to submit a New Drug Application ("NDA") for Infasurf to the FDA. For example, in January 1987, Dr. Gold wrote a memorandum

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7. "Surfactant TA" is the trade name of the Tokyo Tanabe product marketed in Japan.

in which he discussed a conversation he and Dr. Harry Gunkel, Abbott's Director of Clinical Research and Neonatal Medicine, had with Dr. Shapiro. PTX 326. Dr. Shapiro had recently met with Dr. Strauss at the FDA. Dr. Gold reported that Dr. Strauss "was prepared to approve an NDA for CLSE based on the Egan and Enhorning published studies" and that "Dr. Egan is preparing the submission at this time." Dr. Gold also noted the concerns voiced by Dr. Shapiro that Dr. Egan "will have an approved NDA before [Abbott] . . ."

In February 1987, Michael Haney, Abbott's Director of Regulatory Affairs, wrote a memorandum in which he discussed the Infasurf clinical trials and noted that "ONY . . . may have enough data to submit an NDA." PTX 248. In February 1989, Dr. Gold received a memo from Dr. Gunkel discussing a conversation between Drs. Gunkel and Shapiro. Dr. Shapiro "urged [Abbott] to 'get aggressive' about Egan's uncontrolled work and the damage it might be doing at FDA and in the public eye." PTX 333.

Abbott was well aware of the progress of Infasurf because Infasurf was widely used at clinical centers where Abbott had representatives. Since 1983, Infasurf has been the subject of about 13 clinical trials, involving approximately 55 institutions and 100-200 investigators. Approximately 16,000 babies in this country were treated with Infasurf before Abbott finally said anything about possible infringement in June 1994. Tr. 4883-84, 4897-98, 4901.

Abbott was also aware of Dr. Egan's work because he and his colleagues regularly reported their work in the scientific literature, as well as at meetings, seminars, and

conferences attended by Abbott and its consultants. Altogether, Dr. Egan published approximately forty abstracts and papers relating to CLSE or Infasurf. Dr. Notter published over 200 such abstracts and papers concerning surfactants. Yet, until 1994, Abbott remained silent.

Significantly, in addition to following the development of CLSE, Abbott was aware that Dr. Egan believed that CLSE was not covered by any patents. For example, in 1985, ONY applied to the FDA for Orphan Drug status for Infasurf. At the time, Orphan Drug status was only available for drugs that were not covered by a patent.[8] Abbott knew that Infasurf had received this status because it had a copy of the "Pink Sheet" (a widely distributed trade publication) that reported this information, and because they requested and received information about ONY's Orphan Drug status from the FDA.[9] PTX 246, 296.

Abbott also was aware of Forest's activities related to Infasurf. Abbott had access to various trade publications, such as the Pink Sheets, reporting the agreement between ONY and Forest to market the Infasurf product. For example, the

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8. *See* Orphan Drug Amendments of 1985, Pub. L. No. 99-91, § 2, 99 Stat. 387, 387 (1985).

9. Abbott knew from other sources as well that ONY believed, and was telling others, that Infasurf was not the subject of patents. For example, Abbott's files included a newspaper article in which ONY described its product as unpatentable. PTX 50. In 1991, the Pink Sheet also reported that Infasurf was not patentable. PTX 813.

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July 15, 1991 Pink Sheet produced from Abbott's files reported:

> *Forest Labs Licenses ONY's Infasurf Lung Surfactant* under an agreement disclosed in Forest's recently released annual report for the fiscal year ended March 31.'We have just completed a license arrangement with ONY, Inc. covering a surfactant for use in neonatology units which we believe is a superior product in a rapidly growing market,' Forest said.

PTX 813.

In addition, in 1991, an Abbott document records that Forest is "the companybacking Infasurf." PTX 56. And in October 1993, an Abbott consultant attended aForest seminar at which Infasurf was discussed. PTX 1193.

3. Abbott's Motive

While motive is not an element of equitable estoppel that must be proven in order to successfully assert that defense, in this case, understanding Abbott's motive reveals the misleading nature of its conduct. An obvious question here is why Abbott would continue to encourage Dr. Egan, a potential competitor, in his efforts to develop CLSE even after Abbott had decided to develop the Tokyo Tanabe product. The evidence adduced at trial shows that Abbott did so because it wanted to keep its options open in the event that Survanta, the product Abbott had developed based on the Tokyo Tanabe patents, was not approved by the FDA for

commercial sale or did not work out for some other reason. In other words, Abbott was betting on two horses—if efforts to develop Survanta failed, Abbott could turn to ONY and CLSE. Once Abbott finally got FDA approval for Survanta, however, it stopped stringing Dr. Egan along, cut off all contact with him, and eventually asserted an infringement claim against ONY and Forest.

This finding regarding Abbott's motive is based on reasonable inferences drawn from all the facts and circumstances in this case. The following summary of facts highlights the Court's reasoning:

a. In 1983, while it was negotiating with Tokyo Tanabe, Abbott met with Dr. Egan and his group to learn about CLSE. In 1984, even after it had taken a license under the Tokyo Tanabe patents, Abbottrequested the MOI from Dr. Egan and his group and expressed itswillingness to work with them to develop CLSE.

b. In March 1984, Abbott had not started clinical trials with Survanta. In fact, Abbott did not know whether "an IND [would] be possible using the Tanabe product" and believed that "the chances seem small." PTX 317.

c. In June 1985, the FDA granted ONY Orphan Drug status for CLSE. Abbott knew about this. By March 1986, ONY had received a

treatment IND to conduct clinical trials. By July 1986, Abbott knew about those clinical trials. PTX 246.

d. In 1986, Drs. Sauls and Gold went to Buffalo to meet with Dr. Egan to discuss possible joint development of CLSE and to clarify any misunderstandings. They understood that Dr. Egan was angry at Abbott and wanted to keep him friendly. At that time, Abbott still did not have approval to market Survanta. After the meeting, Abbott wrote Dr. Egan a letter suggesting future collaboration between ONY and Abbott.

e. Abbott was still concerned in 1987 about the FDA's review of Survanta and was afraid that ONY might "somehow achieve[] approval first" and thus "be able to secure seven years [sic] market exclusivity." PTX 248, 326.

f. On July 1, 1991, Abbott received FDA approval for Survanta. The December 1990 Abbott-sponsored conference was the last Abbott-sponsored conference to which Dr. Egan was invited. Dr. Notter's consultancy also terminated in 1991.

g. At no time between 1983 and June 1994 did Abbott ever mention to Dr. Egan or ONY that CLSE or Infasurf might infringe the Tokyo Tanabe patents.

h. After Dr. Egan and ONY found another pharmaceutical company to invest in developing Infasurf, Abbott asserted its infringement claim.

4. Abbott's Explanations

Abbott denies that it was stringing Dr. Egan along and has advanced several justifications for its delay in asserting an infringement claim. However, the Court finds none of them persuasive.

First, Abbott contends that it cannot be faulted for not asserting an infringement claim earlier, because up until 1995, when ONY filed its NDA with the FDA, Abbott was barred from asserting infringement under the so-called "safe harbor" provision contained in 35 U.S.C. § 271(e)(1). As explained in detail *infra*, the Court finds this contention wholly without merit.

Second, Abbott contends that it did not assert an infringement claim earlier because it did not regard ONY as a competitive threat. Abbott's own documents, however, belie this contention. Those documents show that Abbott was: (1) closely monitoring ONY's activities; (2) concerned about competition from Infasurf; (3) looking for ways to slow ONY down; and (4) aware of ONY's Orphan Drug status. *See* PTX 42, 44, 46, 50, 56, 244A, 246, 248, 296, 325, 326, 333, 334, 335, 812, 813, 1193. Indeed, Abbott characterized ONY as "creating a major competitive situation." PTX 335. And, Abbott wrote to Dr. Fujiwara and Tokyo Tanabe telling them that ONY was a competitor and advising Dr. Fujiwara not to

assist Dr. Egan's collaborators. PTX 42, 46. Moreover, even if it is accepted as true that Abbott did not view Dr. Egan and ONY as a real competitive threat, this would still not explain why Abbott actively encouraged Dr. Egan and ONY to continue their efforts to develop Infasurf, a potential rival.

Finally, Abbott claims that until it ran tests on CLSE and Infasurf in 1995, it did not know the complete composition of those substances and, therefore, could not have known that there was infringement. This simply is not true. Abbott had been provided with samples of CLSE in 1984 and knew as much about CLSE then as it did in 1994 when it finally sent the letter asserting an infringement claim. Thus, Abbott could as easily have written a letter in 1984 as it did in 1994.[10]

5. Summary of Misleading Conduct

In sum, in light of Abbott's prior relationship with Dr. Egan and ONY and its knowledge of their activities, Abbott's failure to mention possible infringement before 1994 was sufficiently misleading to amount to bad faith. When Abbott gave Dr. Egan its opinion on the patentability of CLSE in 1984, it had a clear duty to mention that CLSE

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10. Another possible reason for Abbott not asserting an infringement claim earlier is that Abbott itself did not believe that CLSE infringed the Tokyo Tanabe patents because CLSE was a lavage, not a minced product and had no additives. Indeed, Abbott told the CLSE developers that the Tokyo Tanabe product was different from prior surfactants and patentable because it was a minced product reconstituted with additives. Tr. 3358-59. Of course, Abbott now denies that it ever believed that CLSE did not infringe the patents.

might already be covered by the Tokyo Tanabe patents, yet it did not. In fact, from 1983 to 1994, Abbott never even hinted to Dr. Egan that CLSE might infringe the patents. To the contrary, Abbott actively encouraged Dr. Egan to continue his work on CLSE. Abbott was leading Dr. Egan on so that it could use him as a fall-back position if necessary. Such conduct was certainly "misleading" under any definition.

B. ONY's and Forest's Reliance

The Court finds by a preponderance of the evidence that ONY and Forest relied on Abbott's misleading conduct. Abbott's misleading conduct lulled Dr. Egan and ONY into believing that Abbott would not assert the Tokyo Tanabe patents against them. For example, Dr. Egan testified that he relied on Abbott's conduct when he made the decision to start ONY in 1985:

> Q. Now, did the fact that Abbott had not suggested to you that Infasurf might infringe its patents, did that fact play any role in your decision to start ONY?
>
> A. Well, it was an absolutely necessary condition to start ONY.
>
> Q. Can you explain that?
>
> A. Well, to — if there had been even the suggestion that we might infringe patents by somebody as large as and as powerful as

> Abbott, it would have been foolhardy and nonsensical to start the ONY company.

Tr. 5006-07.

He also testified that the fact that Abbott had not raised an infringement claim was an "absolutely necessary" basis for his decision, in 1989, to resign as head of Newborn Medicine at Children's Hospital and to take a part-time position at the U.B. Medical School in order to devote more time to ONY:

> Q. Now, did the fact that Abbott didn't suggest that Infasurf might infringe, after ONY was founded, play any role in your decision in 1989 to change your positions at the hospital and at the university?
>
> A. Again, it was an absolutely necessary position, because had Abbott even suggested that we might infringe the patents, the possibility of litigation such that [it] is would have made it impossible to continue.

Tr. 5007; *see also* Tr. 4798-99, 6028.

Dr. Egan also relied on Abbott's conduct in 1985 when he represented to the FDA that Infasurf was entitled to Orphan Drug status because it was not covered by patents.[11] As Dr. Egan explained,

> Q. Now, did your experience with Abbott and the discussions that you had with them in

11. As stated above, at that time, Orphan Drug status was not available to patented drugs.

1983 and 1984, and the correspondence, play any role in your willingness to tell the FDA that Infasurf was not covered by patents?

A. Yes, it did.

Q. And what role did it play?

A. Well, it was obviously the basis on which I told the FDA in conversations that our material wasn't patentable.

Tr. 6028.

Dr. Egan also testified that in 1991, Abbott's conduct was "an absolutely necessary condition" to ONY's warranty to Forest that ONY was the sole and exclusive owner of the rights to Infasurf and to ONY's agreement to indemnify Forest for the cost of settling any claims brought by any third parties. Tr. 5031-32, 6028.

Forest, too, relied on Abbott's conduct when it decided to commence and later to continue its relationship with ONY. Forest knew about the Tokyo Tanabe patents at the time of Forest and ONY's negotiations and that the Tokyo Tanabe patents were licensed to Abbott. Indeed, in the initial presentation that ONY made to Forest, materials were distributed which stated "Abbott Laboratories-bovine-derived product, *Survanta*, licensed from Tokyo Tanabe." PTX 1187.

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In addition, during the initial negotiations between ONY and Forest, Dr. Egan told Forest about his contacts with Abbott and the opinion of Abbott's patent counsel that CLSE was not patentable. Dr. Egan also told Forest about Infasurf's Orphan Drug status, the IND for Infasurf, and the clinical use of Infasurf in thousands of babies.

The fact that Abbott had asserted no patent claim against ONY reasonably led Forest to believe that there was no patent infringement problem and was a major factor in Forest's decision to enter the Forest/ONY agreement. Harold Solomon, the President of Forest, explained that at the time of the Forest/ONY agreement Infasurf had been available for ten years and "nobody raised any objections to it over that ten-year period." Tr. 4002-03, 4126-27, 4302.

Dr. Ronald Albano, who between 1990 and 1996 was Forest's Corporate Vice President of Licensing, testified that he carefully considered the history between Abbott and ONY during his consideration of whether Forest should enter an agreement with ONY:

> Well, we, in doing our due diligence, were quite comfortable with the fact that Dr. Egan had an open relationship with Abbott. And they were aware of the development of Infasurf. And this was 1990. He had presented the product to them in 1983, seven years had gone by, and a lot of events that were in the public domain had occurred, which all gave — all of these events gave us great comfort. Because if there had been any problems with Abbott, they would have

> emerged. There would have been some indication of a problem. And the fact that there hadn't been any, it just confirmed our own belief that there wasn't any problem.

Tr. 4694-95.

Dr. Albano also acknowledged that Forest was a risk-averse company:

> And in all cases, we looked for products that had the bulk of the development done. Because we were a very risk-averse company. And we sought to take products that had proven safety record, proven clinical efficacy, and a clean track record in terms of any hindrances, including any legal — pending legal actions or possible patent problems.

Tr. 4669.

Mr. Solomon also testified that Forest was a risk-averse company that sought to license "proven" products without potential patent problems. Tr. 4669. He explained that Forest would have avoided a known risk of a patent infringement lawsuit with Abbott:

> Q. Now, let's go back to 1991 for a minute. As far as you were aware, at the time of the Forest-ONY agreement, had anyone made a claim that Infasurf infringed the patent?

A. No.

Q. And did that knowledge play any role in your decision to enter into the Forest-ONY relationship?

A. Yes, it did.

Q. And can you explain that role?

A. Well, if somebody made a claim for a patent infringement, we would have had to reconsider whether we wanted to go ahead with the transaction, because we don't want to buy a lawsuit, take the risks of a patent lawsuit, or the expense or the delays involved in a lawsuit. It would have increased the risk of the transaction, every transaction has a certain risk, is the product going to be approved, is it going to be successfully marketed. Are you going to have a problem whether you're going to be able to sell a product at all. You have to take that as an additional risk element. And if a major company like Abbott was going to claim patent infringement, I'm pretty certain we would not have gone ahead with the transaction.

Q. Does Forest have a philosophy about the type of products it licenses?

A. Yes.

Q. And what's its philosophy?

A. Well, we have never licensed a product that had a patent problem with it. And we license products from other companies all the time, and look at products all the time, and we certainly don't want to get involved in patent lawsuits.

Tr. 4126-27.[12]

Had ONY and Forest been on notice of Abbott's intention of asserting the Tokyo Tanabe patents, they could have taken steps to avoid further harm, such as declining to pursue further development of CLSE or altering the chemical composition of CLSE to avoid an infringement claim. But, in light of the nature and circumstances of ONY's relationship with Abbott and the communications between them, there was no reason for ONY or Forest to anticipate that Abbott intended to or was likely to assert the Tokyo Tanabe patents. Thus, there was no reason for ONY and Forest to take any steps to protect themselves. The fact that ONY and Forest failed to insulate themselves from Abbott's infringement claims and, instead, continued to invest heavily in Infasurf is strong proof of reliance.

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12. Although the Court recognizes that the testimony of Dr. Albano and Mr. Solomon was self-serving, the Court found these witnesses wholly credible and gives full credence to their testimony.

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Abbott argues that ONY and Forest cannot be found to have relied upon Abbott's conduct because Dr. Egan, based on his own review of the patents, believed that CLSE and Infasurf did not infringe the Tokyo Tanabe patents. The Court finds this argument without merit.

The evidence adduced at trial showed that Abbott's misleading conduct significantly contributed to Dr. Egan's belief that there was no infringement. Although Dr. Egan did testify that in 1986, he reviewed the Tokyo Tanabe patents and concluded that CLSE did not infringe them, he also testified repeatedly and credibly that his conclusion was based in part on his history with Abbott and what Abbott had told him. Tr. 5849-50, 6010, 6026-28. The fact that Abbott said nothing about infringement for eleven years confirmed Dr. Egan's belief that there was no infringement. *See A. C. Aukerman*, 960 F.2d at 1044 ("The length of the delay also favors drawing the inference because the longer the delay, the stronger the inference becomes.").

Under Abbott's theory, equitable estoppel would never apply to an alleged infringer who relied both on the patentee's conduct and his own belief that his product does not infringe. The fact that Dr. Egan might have believed that his product did not infringe the patents does not negate his reliance on Abbott's misleading conduct. "To hold that [an alleged infringer] who believes his device does not infringe, but who also relied upon the inaction of the patentee may not assert the defense of equitable estoppel, is contrary to the principles of equity." *ABB Robotics*, 828 F. Supp. at 1398 n.27; *see also Adelberg Labs., Inc. v. Miles, Inc.*, 921 F.2d 1267, 1274 (Fed. Cir. 1990) (finding that the alleged infringer's

"generation of documents in anticipation of being sued" did not indicate that it had abandoned its claim to an estoppel defense and noting that "certainly [the alleged infringer] might have reasonably believed that [the patentee] had abandoned its claim, but still wanted to prepare itself in case [the patentee] did bring a claim against it"); *Advanced Hydraulics*, 525 F.2d at 479 (finding reliance on patentee's misleading conduct even though infringer also had informed patentee that infringer's internal investigation indicated there was no infringement); *Wafer Shave*, 857 F. Supp. at 123 ("In this case, [the alleged infringer] was advised by its counsel that it was not infringing the patent. The fact that [the alleged infringer] may have relied in part on this advice does not negate the fact that it also relied on the patentee's apparent abandonment of [its] infringement claim.").

In sum, Abbott's misleading conduct would have lulled any reasonable person in Dr. Egan's position into believing that Abbott did not intend to assert the Tokyo Tanabe patents against him. After all, Abbott gave every indication that it wanted Dr. Egan to develop CLSE. With Abbott actively encouraging his work, it never would have entered Dr. Egan's mind that Abbott might someday assert an infringement claim against him.

C. ONY's and Forest's Prejudice

The Court finds by a preponderance of the evidence that ONY and Forest will be prejudiced as a result of their reliance on Abbott's misleading conduct if Abbott is permitted to press its infringement claim. This prejudice is both economic and evidentiary.

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The economic prejudice to ONY includes the money ONY has already spent developing Infasurf and the debt that it has incurred and cannot repay as a result of having had to borrow money from Forest to pay the legal fees in this action. As Dr. Egan explained, ONY planned to pay off that loan from the sale of Infasurf. Tr. 5042-43. If ONY cannot sell Infasurf, its only product, it will obviously be bankrupt.

The economic prejudice also includes the severe impact on ONY's employees; eleven employees have already been laid off and the remaining employees will be dismissed from their jobs if ONY is unable to market its only product. Severe economic prejudice will also be suffered by Dr. Egan, who gave up his full-time job at Children's Hospital and his full-time position at the U.B. Medical School in order to run a company that now may be bankrupt.

Forest, too, has suffered economic prejudice. Rita Weinberger, Forest's Director of Finance, testified that Forest spent almost eight million dollars on the Infasurf project from June 1991 through June 1994. Mr. Solomon, Forest's President, testified that Forest has spent "thousands" of hours on the Infasurf project. Tr. 4003-04. If defendants are allowed to assert their infringement claims, Forest will lose its opportunity to recover its investment from the sale of Infasurf.

ONY and Forest have also suffered evidentiary prejudice as a result Abbott's delay in asserting an infringement claim. Documents have been lost and witnesses have died during the time Abbott chose not to alert ONY of possible infringement concerns. Had Abbott not waited eleven years

to assert its infringement claim, ONY and Forest may have had a better chance to present a full and fair defense to infringement and to better support its assertions of invalidity and equitable estoppel.

For example, Dr. Shapiro, who co-authored a number of articles concerning the use of CLL in sheep and who was involved in early discussions with Abbott, died in 1989. Dr. Shapiro would have been able to testify about the development of CLL and the meetings and conversations that he had with Abbott about CLSE. Dr. Notter also testified that Dr. Absolom at Abbott "died a few years ago." Tr. 3365. Dr. Absolom could have testified about the samples of CLSE which Dr. Notter gave him and about what Abbott did with them. He also could have testified about the work he did with Dr. Holm, another colleague of Drs. Egan and Notter.

Relevant documents also are missing which might have been available if not for the passage of time. For example, Dr. Notter testified that certain documents regarding the preparation of CLL batches in 1981 are gone. These documents are significant because Abbott argued to the jury that Dr. Egan had not corroborated the testing of CLL in sheep. Thus, their absence now has prejudiced ONY's legal position.

V. Safe Harbor Provision

Defendants argue that the defense of equitable estoppel cannot be asserted in this case because up until 1995, when ONY filed its NDA for Infasurf with the FDA, defendants were barred from suing plaintiffs for infringement under the

so-called "safe harbor" provision contained in 35 U.S.C. § 271(e)(1), which provides, in relevant part, that:

> [i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs . . .

(emphasis added). Defendants contend that ONY was conducting clinical trials of Infasurf during the 1980's and 1990's for FDA-approval purposes and that they were therefore prohibited by the safe harbor provision from bringing an infringement action against ONY during that time period. Thus, defendants argue, because they were legally prohibited until 1995 from suing ONY for infringement, they should not be barred by the doctrine of equitable estoppel from asserting such a claim now. The Court finds this argument unpersuasive.

First, Abbott initially learned of plaintiffs' product in 1983, before the safe harbor provision became effective in 1984. More importantly, even if defendants were barred by the safe harbor provision from bringing an infringement lawsuit against plaintiffs before 1995 when ONY filed its NDA,[13] there is nothing in the statute that would have prohibited defendants from communicating to plaintiffs

13. 35 U.S.C. § 271(e)(2) provides that the safe harbor provision of § 271(e)(1) ends when an NDA is filed for the purpose of marketing the drug.

before that time that they believed Infasurf infringed defendants' patents and that they intended to bring an infringement claim against plaintiffs if plaintiffs took steps to market the product. *Cf. Scholle Corp.*, 133 F.3d at 1472 n.1. In fact, that is exactly what defendants did in June 1994 when they warned plaintiffs by letter that there was reason to believe that Infasurf may infringe the patents. That warning should have come much earlier and there is nothing in the safe harbor provision that would have prohibited such a warning.[14]

VI. Applicability of Equitable Estoppel to Forest

Abbott argues that it had no relationship with Forest and, therefore, had no duty to advise Forest about possible infringement. Abbott concludes that even if it is estopped from asserting an infringement claim against ONY, it can still assert such a claim against Forest. The Court finds this argument unpersuasive because: (1) under the circumstances of this case, Abbott did have a duty to advise Forest of possible infringement; and (2) as a matter of law, Forest is the beneficiary of any estoppel which applies to ONY.

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14. Defendants did not present any evidence showing that the safe harbor provision actually played a role in their not bringing an infringement claim earlier. Based on the evidence adduced at trial and all the facts and circumstances in this case, it appears that defendants' safe harbor argument is an after-the-fact rationalization for their conduct.

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A. Abbott had a Duty to Advise Forest of Possible Infringement

As discussed above, Abbott had extensive knowledge of ONY's and Forest's activities, including the Forest/ONY agreement and their joint plan to file an NDA. And of course, Abbott was aware of its own history with Dr. Egan and ONY. Having misled ONY and Dr. Egan into believing that it would not assert an infringement claim, and knowing that ONY and Forest had agreed to jointly develop Infasurf, Abbott had a duty, just as it did with ONY, to advise Forest of any possible infringement. Yet Abbott waited until June 1994, three years after Forest starting developing Infasurf, to raise the infringement issue. By remaining silent under these circumstances, Abbott misled Forest into believing that Abbott would not assert an infringement claim.

The other elements of equitable estoppel are also present with regard to Forest. Forest relied on Abbott's silence in its decision to pursue the Infasurf project. Forest knew about the Tokyo Tanabe patents at the time of its negotiations with ONY and that the Tokyo Tanabe patents were licensed to Abbott. Forest was also aware of Dr. Egan's and ONY's relationship with Abbott and the fact that Abbott had never mentioned any possible infringement to them. The fact that Abbott had never asserted a patent claim against ONY was a major factor in Forest's decision to enter the its agreement with ONY.

As a result of its reliance, Forest suffered substantial prejudice. In particular, Forest spent almost eight million

dollars and thousands of hours on the Infasurf project from June 1991 through June 1994, when it first received notice from Abbott.

B. Any Estoppel as to ONY Runs to Forest as a Matter of Law

As a matter of law, Forest is entitled to the benefit of any estoppel as to ONY. The effect of equitable estoppel is to create an implied license. *See Wang Labs., Inc., v. Mitsubishi Elecs. Am., Inc.*, 103 F.3d 1571, 1580 (Fed. Cir.) ("Implied licenses arise by acquiescence, by conduct, by equitable estoppel (estoppel in pais), or by legal estoppel."), *cert. denied*, 118 S. Ct. 69 (1997); *Spindelfabrik Suessen-Schurr Stahlecker & Grill GmbH v. Schubert & Salzer Maschinenfabrik Aktiengesellschaft*, 829 F.2d 1075, 1080 (Fed. Cir. 1987) ("The doctrines of legal estoppel and equitable estoppel have been applied by courts to imply a license."), *cert. denied*, 484 U.S. 1063 (1988). Thus, if Abbott is estopped from suing ONY for infringement, ONY has, in effect, received an implied license from Abbott under the Tokyo Tanabe patents.

Under ONY's implied license, Forest can buy Infasurf from ONY and resell it in accordance with the doctrine of patent exhaustion. Under the doctrine of patent exhaustion, "[a] patent owner's monopoly ends with the first sale or disposition by a patentee, or his licensee acting within the scope of the license, of an article embodying the invention of the patent." *Cyrix Corp. v. Intel Corp.*, 846 F. Supp. 522, 537-38 (E.D. Tex.) (citations omitted), *aff'd without op.*,

42 F.3d 1411 (Fed. Cir. 1994). As stated by the Supreme Court in *United States v. Univis Lens Co.*, 316 U.S. 241, 250 (1942) (emphasis added):

> The patentee may surrender his monopoly in whole by the sale of his patent or in part by the sale of an article embodying the invention. His monopoly remains so long as he retains the ownership of the patented article. But sale of it exhausts the monopoly in that article and the patentee may not thereafter, by virtue of his patent, control the use or disposition of the article.

"The Patent Exhaustion Doctrine applies as well to the disposition of a product under a license as it does to outright sale." *Cyrix Corp.*, 846 F. Supp. at 538 (citing *United States v. Masonite Corp.*, 316 U.S. 265, 278 (1942)).

In this case, ONY received an implied license from Abbott by virtue of equitable estoppel. Under the implied license, ONY may make Infasurf and sell it to anyone it wants, including Forest. Under the doctrine of patent exhaustion, Forest is then free to resell the product without infringing the Tokyo Tanabe patents. *Amstar Corp. v. Envirotech Corp.*, 823 F.2d 1538, 1549 (Fed. Cir. 1987).

Forest is also entitled to the benefit of ONY's estoppel because to hold otherwise would significantly undercut, if not wholly vitiate, the purpose of equitable estoppel. If distributors and customers were not protected by ONY's equitable estoppel, not only would ONY be unable to sell its product to Forest, it would also be unable to sell its product

directly, or through sales representatives, to hospitals or to doctors. In effect, ONY could never sell its product.

Instructive here is the case of *Odetics, Inc. v. Storage Tech. Corp.*, 14 F. Supp. 2d 785 (E.D. Va. 1998). In that case, Odetics sued Storage Tech and two of its customers for patent infringement. In an earlier opinion, the court granted Storage Tech and its customers summary judgment on the ground of laches, thereby precluding Odetics, the patentee, from recovering any damages for infringement occurring prior to the laches cut-off date. *Id.* at 787. The court then held that Odetics could not obtain an injunction prohibiting Storage Tech's customers from future use of infringing products purchased during the laches period. *Id.* at 790. Otherwise, according to the court, "what the law takes away with one hand by virtue of laches, it would effectively give back, in whole or in part, with the other, by issuing an injunction against future use of laches products." *Id.* In effect, the equitable protection traveled with the product.

The same principle applies in this case. If Abbott is estopped from asserting its patents against ONY, but is not estopped from asserting its patents against ONY's customers, the law will have taken away from ONY with one hand what it gave to ONY with the other. That result would essentially deprive ONY of its equitable estoppel defense.

VII. Applicability of Equitable Estoppel to Tokyo Tanabe

Tokyo Tanabe argues that, even if it is assumed that Abbott should be estopped from asserting a claim of infringement in this case, the estoppel should not apply to

Tokyo Tanabe as it was not involved in any of the misleading conduct attributed to Abbott. The Court agrees that plaintiffs have failed to show by a preponderance of the evidence that Tokyo Tanabe should be estopped based on its own conduct. While the evidence shows that Tokyo Tanabe was aware of ONY's and Forest's activities, there was no relationship between Tokyo Tanabe and the plaintiffs, like there was between Abbott and the plaintiffs, that created a clear duty to speak. Tokyo Tanabe simply stayed in the background and remained silent. And, as stated above, mere silence, without more, does not constitute misleading conduct for purposes of equitable estoppel. Thus, Tokyo Tanabe cannot be held to be estopped based on its own conduct in this case. Nevertheless, the Court finds that the estoppel against Abbott must be imputed to Tokyo Tanabe as a matter of law.

Abbott is Tokyo Tanabe's exclusive licensee in the United States. An exclusive licensee is, in effect, a co-owner of the patent. As the Federal Circuit has explained: "where all substantial rights under the patent have been transferred in the form of an exclusive license," the licensee is "the virtual assignee." *Enzo APA & Sons, Inc. v. Geapag A.G.*, 134 F.3d 1090, 1093 (Fed. Cir. 1998).

The license agreement between Abbott and Tokyo Tanabe demonstrates that Abbott is, in essence, a "virtual assignee" or co-owner of the Tokyo Tanabe patents. *See* PTX 20. Under the license agreement, Abbott has the exclusive right to make, use, or sell the patented invention in the United States. Abbott also has the right under the license to sublicense others without Tokyo Tanabe's consent and the right to sue for infringement. In fact, under these circumstances, Abbott

enjoys even more rights than Tokyo Tanabe as Tokyo Tanabe has relinquished its right to practice the patent in the United States.

The actions taken by Abbott and Tokyo Tanabe in this case also reflect Abbott's status as a co-owner of the patents. Abbott, by itself, raised the issue of infringement when it wrote the 1994 letter to Forest. Further, Abbott, in its own name, counterclaimed for infringement. It would not have had standing to do so unless it was, in effect, the patentee. *Textile Prods., Inc. v. Mead Corp.*, 134 F.3d 1481, 1484 (Fed. Cir.) ("A licensee is not entitled to bring suit in its own name as a patentee, unless the licensee holds 'all substantial rights' under the patent. Such a licensee is in effect as 'assignee' and therefore a patentee."), *cert. denied*, 119 S. Ct. 73 (1998). Indeed, during opening statements at trial, Tokyo Tanabe's own counsel stated that Abbott, as the exclusive licensee, is "in a sense . . . like the owner [of the patents] in the United States." Tr. 617-18.

The fact that Abbott and Tokyo Tanabe are co-owners of the patents is significant because the Federal Circuit has held that a co-owner of a patent has the right to license others. *Schering Corp. v. Roussel-UCLAF S.A.*, 104 F.3d 341, 344 (Fed. Cir. 1997). That right "does not require the consent of any other co-owner." *Id.* Once a co-owner has issued a license, another co-owner cannot sue the licensee for infringement.

Here, Abbott, as a co-owner of the Tokyo Tanabe patents, has the right to license others without the consent of Tokyo Tanabe. Once such a license is issued by Abbott, Tokyo

Tanabe is bound by the license and cannot sue the licensee for infringement. As stated above, Abbott has conferred, through equitable estoppel, an implied license to ONY and Forest. Accordingly, that license binds Tokyo Tanabe as a matter of law and prevents it from asserting an infringement claim against ONY and Forest.[15]

Any other result would be fundamentally unfair and undercut the purpose of the equitable estoppel defense. A patent owner should not be able to hide behind a licensing agreement and then leap out to assert its patent when its licensee has already misled the alleged infringer into believing that the patent would not be enforced. Because Tokyo Tanabe has received the benefits of the exclusive license to Abbott, it is only fair that Tokyo Tanabe also bears the consequences of Abbott's misleading conduct. *See Adelberg*, 921 F.2d at 1273 (affirming district court's finding that the patentee "was answerable for [its exclusive licensee's conduct] as well as its own").

Allowing Tokyo Tanabe to pursue an infringement claim at this point would render ONY's and Forest's equitable estoppel defense meaningless. The fact that Abbott is estopped from asserting an infringement claim will be of little solace to ONY and Forest if Tokyo Tanabe is still allowed to pursue such a claim. If Tokyo Tanabe is allowed to proceed, even though Abbott is not, the bottom line result will be the same as if Abbott were not equitably estopped; ONY and

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15. Plaintiffs also argue that Tokyo Tanabe should be estopped as a matter of law under the doctrines of privity and inherent authority. In light of the Court's holding, it need not address these issues.

Forest will not be allowed to sell Infasurf. Such a result would allow Abbott to escape the consequences of its misleading conduct and would leave ONY and Forest without a remedy, even though they were clearly misled.

Moreover, the Court finds that, under the circumstances present here, such a result is not unfair to Tokyo Tanabe. Although there was insufficient evidence in this case to support a finding of equitable estoppel against Tokyo Tanabe based on its own conduct, Tokyo Tanabe was not a totally innocent party. As discussed above, Abbott kept Tokyo Tanabe apprised of the development of CLSE and warned Tokyo Tanabe that Dr. Egan and ONY were potential competitors. PTX 46. Yet Tokyo Tanabe did nothing to protect its patent rights.

Nor will Tokyo Tanabe be left without a remedy, as it can still sue Abbott for breach of the licensing agreement. Indeed, Tokyo Tanabe's counsel stated during oral argument on the post-trial motions that had Tokyo Tanabe not been named as a defendant in this case and had Abbott been found to be equitably estopped from asserting an infringement claim, Tokyo Tanabe would have sued Abbott for breach of contract. See Transcript of January 15, 1999 at 153. There is nothing to prohibit Tokyo Tanabe from suing Abbott now.

In sum, the doctrine of equitable estoppel is a doctrine of fairness and estopping Tokyo Tanabe as well as Abbott is the only fair and equitable result in this case.

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CONCLUSION

For the reasons stated, the Court holds that the defendants, Tokyo Tanabe and Abbott, are barred by the doctrine of equitable estoppel from asserting infringement of the patents in suit against the plaintiffs, ONY and Forest. The Clerk of the Court is hereby ordered to enter judgment in favor of the plaintiffs and to take all steps necessary to close the case.

IT IS SO ORDERED.

s/ Richard J. Arcara
HONORABLE RICHARD J. ARCARA
UNITED STATES DISTRICT JUDGE

Dated: June 23, 1999